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No. 08-543

IN THE

Supreme Court of the United States

LAWRENCE R. POLINER, M.D., AND
LAWRENCE R. POLINER, M.D., P.A.,
Petitioner,

v.

TEXAS HEALTH SYSTEM, DOING BUSINESS AS PRESBYTERIAN HOSPITAL OF DALLAS, TEXAS, A TEXAS NON-PROFIT CORPORATION, AND JAMES KNOCHEL, M.D.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE* AND BRIEF OF *AMICUS CURIAE* SEMMELWEIS SOCIETY INTERNATIONAL, INC.

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MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE*

COMES NOW, SEMMELWEIS SOCIETY INTERNATIONAL, INC., by and through counsel and files this its Motion to File Amicus Curiae Brief without the consent of the Petitioners to this matter.

Respectfully submitted,

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BRIEF OF *AMICUS CURIAE* SEMMELWEIS SOCIETY INTERNATIONAL, INC.

INTEREST OF *AMICUS CURIAE*

Amicus SEMMELWEIS SOCIETY INTERNATIONAL, INC. (SSI) is a non-profit organization of physicians, nurses, and healthcare professionals. SSI's mission is to promote better-safer-less-costly healthcare for all Americans.[1]

SSI encourages healthcare professionals to work conscientiously for patients' welfare and safety, and

[1] No contributions by parties.

to advocate for appropriate patient treatments, even when pressured by hospitals and physician-colleagues to over-or-undertreat patients. When doctors, nurses, and technicians are effectively shielded from retaliation, on-site professionals can follow their ethical duties and put the patient first. Now, per *Poliner v. Texas Health Systems,* 537 F.3d 368 (5th Cir. 2008), the Health Care Quality Improvement Act (42 U.S.C. § 11111 et seq. (1986)(HCQIA)), empowers management to openly retaliate against conscientious physicians without accountability.

This Court ruled in *Pegram v. Herdrich*, 530 U.S. 211, 219-220 (2000), that physicians are expected to ignore pressures to undertreat patients and provide "covered services with a reasonable degree of skill and judgment in the patient's interest." *Pegram* involved financial incentives if physicians delayed tests, but *Poliner* takes *Pegram* to extremes by expecting physicians to serve patients' best interests after stripping away doctors' few remaining HCQIA protections against badfaith peer-review.

Departing from prevailing interpretations by other federal circuits (see below), *Poliner* allows unprecedented use of medically questionable evidence to proclaim peer-reviewers' actions immune from damages. Presbyterian's peer-review actions against Dr. Poliner were held "objectively reasonable," even though the jury specially found that peer-reviewer malice and badfaith drove the adverse actions. Yet the Fifth Circuit overruled the jury, affirming peer-reviewers' badfaith actions as "objectively reasonable" (*Poliner v. Texas Health Systems* 537 F.3d at 379-380, 384-385).

ISSUES PRESENTED

Amicus requests consideration of three related issues.

1. Because *Poliner* interprets HCQIA's "objectively reasonable test" for peer-reviewer immunity contrary to several other circuits by substituting common law fiat for clearly worded statutory and legislative intent, ought this Court resolve the conflicts?

2. For the great majority of hospitals who elect Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation as final federal certification to deem them compliant with MEDICARE Conditions-of-Participation (CoP) and automatically eligible for MEDICARE payments, are JCAHO accreditation standards binding regulations governing patient care and peer-review for clinical privileging?

3. Because the *Poliner* decision was only eight days after Congress declared on July 15, 2008 that JCAHO had "unique deeming authority" to certify and deem hospitals MEDICARE-compliant, which precluded the Fifth Circuit's considering how JCAHO standards for peer-review proceedings may regulate clinical privileging by suffusing HCQIA's fairness and due process guarantees for peer-reviewed physicians, should the decision-timing issue be consolidated with this Court's determining how HCQIA ought to be interpreted?

BACKGROUND OF PHYSICIAN DUE PROCESS ISSUES

Besides stopping physicians from monitoring patient care and safety, *Poliner* has silenced those best situated to report healthcare overtreatment and MEDICARE fraud. Doctors rarely talk about it, but they all know what happens if they question or report billings for unnecessary treatment or other MEDICARE fraud.[2]

Michael J. Myers, healthlaw and healthcare business administration professor, spent 17 years as counsel and CEO of nonprofit hospitals before returning to university. He understands the organizational and financial forces driving healthcare. In March 2008 (four months before the *Poliner* decision), Myers gave an example from a hospital operated by the Mayo Clinic.

> [T]he fundamental corporate restructuring the United States healthcare system has undergone, since the enactment of HCQIA . . . [has] implications for physicians who now overwhelmingly are "employees" of large, integrated, and economically and politically influential healthcare systems. We should dwell upon the influence of such corporate integration upon physician behav-

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[2] Yann Van Geertruyden, in *The Fox Guarding The Henhouse: How The Health Care Quality Improvement Act of 1986 and State Peer Review Protection Statutes Have Helped Protect Bad Faith Peer Review In the Medical Community, 18 J.Contemp.Health Law 239 (2001), told Alan Ullberg how his physician-father suffered badfaith peer-review when he refused to join a medical group, a family experience that informed the son of badfaith peer-review (and too-credible threats of it) as the "problem in the medical profession which is known by many, but spoken of by few."*

> ior and increased risk for a physician who does not adhere to the clinical and financial forces that drive system profitability. Last semester I had a former Mayo pediatric oncologist confirm how corporatization of Mayo has affected clinical judgment and [physician] autonomy. The employed physician who suggests that certain diagnostic and surgical procedures may be unnecessary and not in the best interests of patient care may be frustrating utilization targets and undermining the "production" incentives found in the contracts of employed physicians. The CEO/CFO and Medical Director will likely be offended with such conduct, as will fellow physicians who stand to profit from increased "clinical production."[3]

Poliner heightens what Professor Myers calls the "... increased risk for a physician who does not adhere to the clinical and financial forces that drive system profitability." Since *Poliner*, any evidence hospital managers put in the record that indicates a targeted physician may have provided substandard patient care, will support a peer-review action even if the fact finder establishes malice and badfaith.

A physician can win at trial only to have an appellate court cherry pick evidence from the record to make its *de novo* finding of "objective reasonableness." Affirming badfaith peer-review actions plays right into the hands of the managers of hospitals, profit and nonprofit, increasingly driven by the bottom line,[4]

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[3] E-mail to Alan Ullberg from Professor Myers, March 25, 2008, in Ullberg's files.

[4] Michael Myers, 51 S.Dak.L.Rev. 465, 466 (2006), commenting how nonprofit regional hospitals "typically enjoy oligopolistic

Doctors are human. They make mistakes just like everyone who drives a car. It is well known among police officers that closely observing any driver will reveal a continuous series of inconsequential technical infractions. A trained police officer can appear in court and present his observations as "key evidence" to support a judgment of "safety risk." A reviewing court will likely affirm the trial court's judgment based on that finding. Under this scenario, any driver can be adjudicated "unsafe," just like any physician can be adjudicated a patient-safety risk.[5]

The Fifth Circuit's extreme standard for HCQIA judicial review allows an appellate court of lay judges, not trained in medicine, to make medical judgments. Judges affirm and immunize medically sloppy, bad-faith peer-review actions driven by malice, which can destroy a physician's reputation and career for being human. Handpicked "evidence" from the record sustains peer-reviewers' malicious actions as "objec-

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market power in a region . . . [so] physicians, executives, board members, and their aligned business interests are able to place private interests ahead of their presumed public interest without significant risk of detection or penalty. These modern, multi-billion-dollar health systems earn revenues . . . to accommodate their collective interests, attracting an array of entrepreneurial constituents because, to quote bank robber Willie Sutton, that is 'where the money is.' . . . These . . .are bottomless, in part, because of the conflicts between the stated missions of hospital systems and their actual performance in the market."

[5] Shannon Brownlee, Overtreated: Why Too Much Medicine Is Making Us Sicker and Poorer (2007), quoting a surgeon that "good doctors make mistakes too. . . .[E]very physician is destined to make at least one horrible mistake in the course of a career—and most will carry the memory and shame of it for the rest of their lives." (p. 53).

tively reasonable." The kangaroo court-type peer-review affirmed in nearly all HCQIA cases is completely different from the "Objective, evidence-based decisions regarding appointment to the membership on the medical staff," that JCAHO standards prescribe.[6]

Officers and members of SSI attest that, in less than four months, "*The Poliner Principle: "Any evidence of bad medicine, no matter how contrived or flimsy, will support badfaith peer-review actions that are totally unaccountable,*" has chilled the medical community.

There is even less chance than before *Poliner* that those few doctors who might have broken their silence to save a patient from death or serious injury[7] will take the ultimate risk of career and medical license to save a patient's life.[8]

SSI fully supports goodfaith peer-review. Being human, physicians can become impaired, disruptive, or lose their medical skills. But *Poliner* allows all physicians to be smeared as "unsafe," "impaired," or

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[6] In a July 09, 2008 bulletin, *Applicable Joint Commission Standards (see Appendix _____*, JCAHO describes generally the Medical Staff Standard (MS.4.00) for ". . . maintenance of a credible process to determine competency. . . ." That is an objective, professional-medical inquiry, only superficially resembling peer-review actions reviewed and affirmed by lay judges.

[7] SilenceKills.com (see appendix_____) reports that less than 10 % of physicians speak out when they see medical errors, even life-threatening errors. *White Coat of Silence* describes nurses' reluctance to report what they see. (Appendix _____)

[8] See Charles I. Artz's paper, (appendix ____), noting how mandatory reports to a central data bank of the results of clinical privileging proceedings can ruin a good doctor.

"disruptive," because they have been effectively stripped of HCQIA fairness and due process rights.

While the stated objective of peer-review is to protect patients by improving the pool of practicing physicians (good doctors weeding out bad doctors), trending federal court decisions culminating in *Poliner* immunize illegitimate peer-review actions so it is the bad doctors who are both empowered and protected by HCQIA immunity. Because bad doctors bring in more money than good doctors,[9] hospitals are financially pressed to encourage their bad doctors to drive out their good doctors.

The principle in *Poliner* of gravest concern to Amici is the near-absolute deference to peer-reviewers regardless of their motives. Peer-reviewers and the hospital managers who control the peer-review process can professionally discredit any doctor for trumped up reasons; yet such actions are affirmed because any flimsy allegation of substandard medicine meets the *Poliner* test. Hospital managers can credibly threaten otherwise-good physicians with virtually unchallengeable peer-review actions so they act like sheep instead of watchdogs.

Consequences from *Poliner* will continue the high rate of preventable, hospital and physician-caused patient deaths and medical-error injuries. The 1999 study by the Institute of Medicine found there are nearly 100,000 medically-caused patient deaths per year.[10] Each year about 80,000 patients still die

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[9] Brownlee, supra, at p.) (appendix____) for an example how good programs for patient treatment and safety often fail because cost-effective treatment, by definition, is not a big money-maker.

[10] Lucian Leape, M.D. MPH, Appendix _____.

unnecessarily, deaths preventable if available knowledge and techniques had been applied.[11] Bad medicine also costs payers more including the taxpayers.[12]

As a percentage of the Gross National Product, current healthcare spending is about 17 % of Gross National Product and rapidly rising. Physicians, the most knowledgeable and acute onsite monitors of cost-benefit-balanced patient treatment plans oriented to economy, no longer can speak up and challenge excessive treatments and overbillings. Even when they know their hospital is committing massive MEDICARE fraud, they cannot afford to risk career and license just to save taxpayers a few hundred million dollars.[13]

Poliner impacts healthcare quality, safety and cost.

ARGUMENT

I. THE COURT SHOULD GRANT THE PETITION TO RESOLVE WHETHER THE HEALTH CARE QUALITY IMPROVEMENT ACT HAS BEEN DISPLACED BY FEDERAL COMMON LAW

The decision below conflicts with decisions of other federal courts of appeals. It is also utterly inconsistent with this Court's enduring teaching that federal common law is displaced where Congress has directly spoken to a particular subject matter.

Where, as here, "Congress addresses [a] problem formerly governed by federal common law," courts

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[11] HealthGrades, Appendix _____.

[12] *Overtreated*, p.___, Appendix _____.]

[13] The personal and professional consequences to Patrick Campbell, M.D., an unwelcome and unappreciated MEDICARE fraud reporter, are described in *Overtreated, p.*__, Appendix__.

must construe the federal statute at issue with a "willingness to find congressional displacement of federal common law." *City of Milwaukee v. Illinois,* 451 U.S. 304, 317 & n.9, 315 n.8 (1981) (*"Milwaukee II"*) (emphasis omitted). This principle exists because our system of justice dictates that it is for Congress, not the federal courts, to articulate the appropriate standards to be applied as a matter of federal law." *Id.* at 317. As other courts of appeals have recognized, "once Congress has addressed a national concern, our fundamental commitment to the separation of powers precludes the courts from scrutinizing the sufficiency of the congressional solution" or "holding that the solution Congress chose is not adequate." *Illinois v. Outboard Marine Corp.,* 680 F.2d 473, 478 (7th Cir. 1982); see *Milwaukee II,* 451 U.S. at 324. See also *United States v. Oswego Barge Corp.,* (*In re Oswego Barge Corp.*), 664 F.2d 327, 335 (2d Cir. 1981) ("separation of powers concerns create a presumption in favor of [displacement] of federal common law whenever it can be said that Congress has legislated on the subject").

Federal common law is displaced by direct congressional treatment of an issue even if Congress does not expressly state it is displacing common law. See *Resolution Trust Corp., v. Frates,* 52 F.3d 295, 297 (10th Cir. 1995) (". . . to supersede authority previously established by federal judicial ruling, Congress need not affirmatively proscribe that authority, but may do so simply by speaking directly to the issue"); *Milwaukee II,* 451 U.S. at 313-15; *Resolution Trust Corp. v. Miramon,* 22 F.3d 1357, 1360 (Fifth Cir. 1994). This Court has already made clear these principles govern federal statutory interpretation as a general rule. *Firestone Tire & Rubber Co. v. Bruch,* 489 U.S.101, 108 (1989) (quoting *Russell,* 473 U.S. at

146). See also *Xin Liu v. Amway Corp.*, 347 F.3d 1125, 1133 n.6 (9th Cir. 2003) (interpreting Congressional intent under FMLA).

The conflict between federal common law and Congressional intent is illuminated by the Fifth Circuit's decision in the *Poliner* case, as it amplifies the diversity amongst Circuit Courts of Appeal in their interpretations of HCQIA immunity provisions intended by Congress. (42 U.S.C. § 11101-11152 (1988)). Specifically, federal appeals courts have variously interpreted section 11112(a) of HCQIA, which reflects Congress's intent "to encourage good-faith professional review activities of healthcare entities" by offering immunity protections for professional reviewers, "unless the good faith presumption is rebutted by a preponderance of the evidence."

Although lower courts have recognized that Congress intended section 11112(a) (4) of HCQIA to provide immunity for an action only if taken "in the reasonable belief that the action was warranted by the facts known," many Circuit Courts of Appeal have ignored that Congress intended certain fairness standards out of a concern that immunity under HCQIA "might be abused and serve as a shield for anti-competitive economic actions under the guise of quality controls...." H.R.Rep.No. 903, 99th Cong., 2d Sess. 9, *reprinted in* 1986 Code Cong. & Admin.News 6391. The result of this varied interpretation by Circuit Courts has been contradictory federal common law, which attempts to displace Congressional intent behind HCQIA. *See* 1986 Code Cong. & Admin. News 6392-93). A few notable decisions in the Third, Fourth, Sixth, Eighth and Eleventh Circuits are illustrative of this fact.

The Third Circuit Court in *Bhatt v. Brownsville General Hosp.,* 236 Fed. Appx. 764 (3rd Cir. 2007) has been consistent, in principle, with the dissenting opinion in *Austin v. McNamara,* 979 F.2d 728, 733 (9th Cir. 1992)[14] by acknowledging that some inquiry into the subjective belief or potential actual malice of professional reviewers must be made when determining whether a "goodfaith reasonable belief" existed in a peer-review action. *Bhatt v. Brownsville General Hosp.,* 236 Fed. Appx. 764 (3rd Cir. 2007). Likewise, the Third Circuit would grant a professional review body immunity only from civil damages and thus wrestles with the question of whether summary judgment is appropriate when an anti-trust action is alleged. *Gordon v. Lewiston Hosp.,* 423 F.3d 184 (3rd Cir. 2005). Therefore, the Third Circuit would appear to allow some factual inquiry into ill will or hostile motivations of peer reviewers.

On the other hand, the Fourth Circuit Court in *Braswell* held that "reasonableness" of a belief giving rise to the immunity provisions of HCQIA is determined by quality of investigation by the peer-review body. *Braswell v. Haywood Regional Medical Center,* 234 Fed. Appx. 47 (4th Cir. 2007). Likewise, the Fourth Circuit has held that this "reasonable belief" standard of HCQIA is satisfied if "the reviewers, with the information available to them at the time of the professional review action, would reasonably have concluded that their action would restrict incompe-

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[14] *Austin v. McNamara,* 979 F.2d 728, 733 (9th Cir. 1992) (stating that Congress intended effective peer-review to improve quality of medical care)

tent behavior or would protect patients."[15] Therefore, the Fourth Circuit looks at the totality of the process plus the fundamental fairness and due process of an investigation leading up to the peer-review, as held in *Freilich v. Upper Chesapeake Health*, 313 F.3d. (2002).

Similarly, the Sixth Circuit court in *Meyers v. Columbia/HCA Healthcare Corp.*, 341 F.3d 461, 468 (6th Cir. 2003), has announced that HCQIA creates an "unusual summary judgment standard." That is, "might a reasonable jury, viewing the facts in the best light for [the plaintiff], conclude that he has shown, by a preponderance of the evidence, that the defendants' actions are outside the scope of § 11112(a)?"[16] Accordingly, under *Meyers*, the plaintiff has the burden of overcoming the presumption of immunity by showing that the review process was not reasonable, but retains the right to rebut this presumption.[17] But later, Sixth Circuit joined the Third Circuit in *Talwar v. Catholic Healthcare Partners,* 258 Fed. Appx. 800 (6th Cir. 2007), which holds that the presumption of immunity may be rebutted by a showing of actual malice that is the standard for determining "objective reasonableness". *Talwar v. Catholic Healthcare Partners,* 258 Fed. Appx. 800

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[15] *Bryan,* 33 F.3d at 1323 (citing H.R.REP. NO. 903, at 10, *reprinted in* 1986 U.S.C.C.A.N. at 6392-93). It is an objective standard, rather than a subjective good faith requirement.

Id. (citing *Austin,* 979 F.2d at 734); *Imperial v. Suburban Hosp. Ass'n, Inc.*, 37 F.3d 1026, 1030 (4th Cir. 1994). *See Vistein v. American Registry of Radiologic Technologists,* 509 F.Supp.2d

[16] *Meyers v. Columbia/HCA Healthcare Corp.*, 341 F.3d 461, 468 (6th Cir. 2003)(citing *Bryan v. James E. Holmes Reg'l Med. Ctr.*, 33 F.3d 1318, 1333 (11th Cir. 1994)(quoting *Austin v. McNamara*, 979 F.2d 728, 734 (9th Cir. 1992)).

[17] *Id.*

(6th Cir. 2007). Therefore, the Sixth Circuit would allow evidence of intentionally malicious behavior surrounding a peer-review to rebut the presumption of immunity under HCQIA. Conversely, the Eighth Circuit in *Estate of Blume,* grants professional review body immunity only from civil damages and thus contemplates whether a physician should be entitled to absolute immunity from suit resulting from a sham peer-review action. *Estate of Blume v. Marian Health Center,* 516 F.3d 705 (8th Cir. 2008). Likewise, the Eight Circuit recognizes an aggrieved physician's right to seek judicial remedies under HCQIA, which does not allow money damages, only equitable relief. *Id.* However, another Eighth Circuit Court of Appeals decision in *Lee v. Trinity Lutheran Hosp.,* 408 F.3d 1064 (8th Cir. 2005) fails to follow its prior analysis and simply holds that a reasonable and thus fair investigation by the hospital supports determination of a "reasonable belief," and thus immunity under HCQIA. *Lee v. Trinity Lutheran Hosp.,* 408 F.3d 1064 (8th Cir. 2005). Consequently, the Eighth Circuit looks only to the fairness of the overall peer-review process.

In *Bolt v. Halifax Hosp. Med. Ctr.,* 891 F.2d 810, 821 (11th Cir.) the Eleventh Circuit defines "objectively reasonable" as the instance when no "reasonable medical reviewer" would have reached the same conclusion regarding the legitimacy of a peer-review action. *Bolt v. Halifax Hosp. Med. Ctr.,* 891 F.2d 810, 821 (11th Cir.). Likewise, in *Bryan* the Eleventh Circuit observes that an extensive trial record supported reasonable belief that a peer-review action was taken in goodfaith. *Bryan v. James E. Homes Reg'l Med. Ctr.,* 33 F.3d 1318, 1326-1329 (11th Cir. 1994). The *Bolt* and *Bryan* cases illustrate how the Eleventh Circuit equates a finding that an "objec-

tively reasonable belief" is a factual one that might be left for the jury.

The Circuit Courts of Appeal are independently deciding, on a case-by-case basis, what Congress intended under HCQIA. They all profess to uniformly impose an objective standard of "reasonableness," but differ widely in the degree to which they consider subsidiary issues of fact or the statute's requirement to afford "adequate notice and hearing procedures."[18] Lacking guidance there has emerged an inconsistent body of law, preventing a clear legal definition and understanding of this "objectively reasonable" standard. *Poliner* is a culmination of courts' confusion and trend toward interpreting Congressional intent under HCQIA as granting absolute immunity to peer reviewers. Despite evidence of malice or political and economic competition in peer-review actions, Poliner *held*, "[O]ur sister circuits have roundly rejected the argument that such subjective motivations overcome HCQIA immunity, as we do" (537 F.3d at 379-380). However, this holding by the Fifth Circuit goes much further than any prior decision in the Circuits by holding that the "objective test" means underlying motives and malice of peer reviewers are irrelevant in deciding whether peer reviewers are entitled to HCQIA immunity or not. *Id.*

As illustrated, *Poliner* is inapposite of most other Circuit Courts because, unlike its sisters, it eliminates HCQIA's requirement of fundamental fairness by peer-reviewers. The Fifth Circuit finalized a trend by the courts, which will hold that "the good or bad

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[18] *Supra*

faith of the reviewers is irrelevant."[19] Courts are more likely to deny the possibility that there might be some point at which a belief is not "reasonable;"[20] or that will satisfy a Plaintiff's burden, which rebuts the presumption of immunity under HCQIA as Congress intended.

Poliner [21] purports to uphold the due process and equal protection rights of disciplined physicians, but then boldly implies there is no set of facts that will allow a physician to rebut the "objectively reasonable" standard of HCQIA. In doing so, *Poliner* has finally announced a standard which displaces Congressional intent under HCQIA and flatly denies admissibility of any evidence relevant to rebut the presumption that the defendants possessed a "reasonable belief" the peer- review action was warranted by the facts known.[22]11

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[19] *Poliner v. Texas Health Systems*, 537 F.3d 368, 378 (Fifth Cir. 2008).

[20] *Id.* (citing *Brader v. Allegheny Gen. Hosp.*, 167 F.3d 832, 840 (3rd Cir. 1999).

[21] *Poliner*, 537 F.3d at 378 (holding any action taken with stated purpose of protecting health care is entitled to HCQIA immunity protections). *See also Sugarbaker v. SSM Health Care*, 190 F.3d 905, 912 (8th Cir. 1999)(citing *Brader v. Allegheny Gen. Hosp.*, 167 F.3d 832, 839 (3rd Cir. 1999)(quoting *Bryan v. James E. Holmes Reg'l Med. Ctr.*, 33 F.3d 1318, 1334 (11th Cir. 1994), *cert denied*, 514 U.S. 1019, 115 S.Ct. 1363, 131 L.Ed.2d 220 (1995)).

[22] *See Sugarbaker v. SSM Health Care*, 190 F.3d 905, 912 (8th Cir. 1999)(citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986) (holding that factual dispute regarding reasonableness requires submission to jury); *Austin v. McNamara*, 979 F.2d 728, 734 (9th Cir. 1992)(holding that the standard is whether a reasonable jury would find Defendant's actions outside scope of § 11112(a)).

No allegation of incompetence in a peer-review action needs to be true;. a mere allegation against a physician in a peer-review action will be sufficient to call a doctor incompetent and destroy his medical practice. However, beware, because if mere allegation is sufficient, then no physician will be judged competent because *Poliner* allows peer-reviewers to cherry pick "facts" to support badfaith, sham peer-review actions against any physician.[23]

Poliner displaces Congressional intent under HCQIA and seeks to replace it with federal common law, denying fundamental rights of "physicians [to] receive fair and unbiased review [and] to protect their reputation and medical practices." 1986 Code Cong. & Admin.News at 6393. This extreme *Poliner Rule* must be wound back to where the § 11112(a)(4) "reasonable belief" on the part of the peer-reviewers required to enjoy § 11111(a)(1) immunity is based on all facts in the record, as Congress intended.

The *Poliner* Court goes on to inconsistently hold it is an objective inquiry that considers the totality of the circumstances, citing *Imperial v. Suburban Hosp. Ass'n, Inc.*, 37 F.3d 1026, 1030 (4th Cir. 1994). It also did not matter to the Fifth Circuit that the patient care demanded by the peer-reviewers may not actually be beneficial, in fact harmful, to a patient.

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[23] *Poliner v. Texas Health Systems*, 537 F.3d 368 (Fifth Cir. 2008)(stating "[I]t bears emphasizing that 'the good or bad faith of the reviewers is irrelevant' (citing *Brader v. Allegheny Gen. Hosp.* 167 F.3d 832, 840 (3rd Cir. 1999)). Nevertheless, the *Poliner* Court goes on to inconsistently hold that it is an objective inquiry in which we consider the totality of the circumstances citing *Imperial*, 37 F.3d at 1030. It also did not matter to the Fifth Circuit that the care demanded by the reviewers may not actually be beneficial, or in fact harmful, to a patient.

II. MEDICARE IMPROVEMENTS FOR PATIENTS AND PROVIDERS ACT OF 2008, REQUIRES A SHIFT IN INTERPRETING HCQIA'S FAIRNESS AND DUE PROCESS STANDARDS FOR PEER-REVIEWED PHYSICIANS. AFTER JULY 2008, HCQIA MUST BE INTERPRETED ACCORDING TO JCAHO STANDARDS ISSUED AND ENFORCED PURSUANT TO EXPRESS STATUTORY DELEGATION TO JCAHO FROM THE SECRETARY OF HEALTH AND HUMAN SERVICES.

Procedural aspects of *Poliner* are like *Kennedy v. Louisiana* (decided June 25, 2008, rehearing considered, but modified October 1, 2008). *Kennedy* held the death penalty could not be imposed for rape of a child, not knowing Congress had amended the Uniform Code of Military Justice in 2006 to provide the death penalty for military personnel convicted of child rape.

Similarly, *Poliner* was decided by the Fifth Circuit July 23, 2008, with no awareness by the parties or the Court that Congress passed a law eight days before, on July 15, 2008, fundamentally changing HCQIA's fairness and due process requirements for peer-reviewed physicians. No one realized the effect of the Congressional action until after the time for reconsideration expired on August 6, 2008.

III. HCQIA'S DUE PROCESS, EVIDENTIARY, AND RELATED FAIRNESS REQUIREMENTS

HCQIA profoundly affects how hospitals conduct peer-review proceedings, setting minimum fairness and due process standards that peer-reviewers and peer-review actions must meet to qualify for immunity. What is "fair" to the physician (§ 11112 (a)(3)) or appropriate due process depends on the baseline

assumptions pervading these statutory guarantees, in the factual circumstances under review. Until Congress spoke, courts looked to HCQIA, plus judicial interpretations of the fairness and other notice and due process protections Congress expressly provided physicians who are peer-reviewed.

Unfortunately, courts interpreted HCQIA fairness and due process without understanding that the Act's general fairness and due process requirements have been implemented by a comprehensive set of regulations. These regulations implementing HCQIA's fairness and due process guarantees have been issued in the form of standards for accrediting hospitals that elected to be regularly surveyed and accredited by JCAHO.

By statute (42 U.S.C. § 1395bb) hospitals have the option to be inspected by MEDICARE regulators to be certified as eligible to receive MEDICARE payments, or be accredited by JCAHO.

Instead of federal HHS inspectors periodically investigating whether MEDICARE payment standards are met, nearly all hospitals have elected to be regularly surveyed and accredited by JCAHO. The practical and legal advantage for a hospital is that JCAHO holds delegated governmental power to issue an automatic, immediate and final certification of MEDICARE-compliance. Hospitals can receive MEDICARE payments without submitting to inspection by federal MEDICARE inspectors.

Because of a statute passed in 1965 (42 USC § 1395bb, below) JCAHO accreditation is final. Accreditation is binding on HHS and MEDICARE managers because JCAHO certification "deems" a hospital MEDICARE-compliant. Once JCAHO ac-

credited a hospital, §1395bb did not allow MEDICARE to inspect that hospital to determine if it met MEDICARE rules, called "Conditions of Participation" (CoP). It was not until summer 2008 that HHS regained its deeming authority Congress delegated exclusively to JCAHO in 1965.

Although in legal reality the clinical privileging of physicians was governed by JCAHO accreditation standards used to deem hospitals eligible for MEDICARE dollars, neither healthcare attorneys nor the courts understood that JCAHO holds and exercises government powers. JCAHO has federal functions similar to other quasi-government delegatees like the New York Stock Exchange and the National Association of Securities Dealers (now the Financial Industry Regulatory Authority, FINRA) that regulate securities' transactions for the federal government.

It was not until after Congress passed the Medicare Improvements for Patients and Providers Act (HR 6331), that healthcare attorneys began to understand that JCAHO hospital accreditation standards and yearly updates govern patient care including granting or modifying physicians' clinical privileges.

By a reverse legislative act, revoking the existing delegation to JCAHO of HHS's powers, Congress declared that JCAHO has held and exercised governmental authority. A power must exist to be revoked; and the title of § 125 of HR 6331, was: "REVOCATION OF UNIQUE DEEMING AUTHORITY OF JCAHO."

Since § 125 of H.R. 6331 was passed, we now know that since 1965 JCAHO standards have been, are, and will be until 2010, far more than guidelines for hospitals' management of their medical staffs, for

terms and due process requirements in medical staff bylaws, and the care and safety of patients. By revoking in very express language the delegation of "unique deeming authority," Congress finally made clear that JCAHO is, until 2010, HHS's agent for deeming MEDICARE eligibility.

The consequence of this recognition is that JCAHO issuances and updates in the form of accreditation standards have served as federal (and state, see below) patient care and physician clinical privileging regulations.

These regulations, issued in the form of "accreditation standards," govern all JCAHO-accredited-Medicare-eligible hospitals. JCAHO's *Comprehensive Accreditation Manual for Hospitals* (CAMH) and its frequent updates are the law for JCAHO-accredited hospitals as to patient care and safety and related activities like managing their medical staffs, clinical privileging, and peer-review.

When Medicare began in 1965, the Department of Health, Education and Welfare (HEW, now Health and Human Services [HHS]), lacked in-house expertise to establish and update standards for hospitals' eligibility for MEDICARE payments.

HEW looked to JCAH, a nonprofit formed in 1951 by medical and hospital associations then operating a national accreditation program. JCAH already had the expertise and structure to promulgate, update and enforce hospital standards. By 1965, JCAH surveyed and accredited about 60 % of U.S. hospitals.

So that MEDICARE funds were not paid to substandard hospitals, Congress delegated to JCAH—almost entirely in many respects—the (HEW) Secretary's statutory authority to determine which hospi-

tals met MEDICARE requirements. "JCAHO standards, in fact, became the original CoP"[24]. As passed in 1965, §1395bb of 42 U.S.C. provided (with exceptions not relevant here):

> . . . [I]f . . . an institution is accredited as a hospital by [JCAHO], and
>
> . . . [the Secretary or a State agency the Secretary may designate is provided] . . a copy of the most current accreditation survey of such institution . . . then, **such institution shall be deemed to meet [MEDICARE Conditions of Participation, as provided in 42 U.S.C. § 1395x et al.].** (Emphasis added).

CAMH standards for medical staff bylaws and physician credentialing have not been advisory standards as most healthcare attorneys and courts assumed. Despite the failure of attorneys and courts to comprehend until Congress so declared, JCAHO has had governmental powers.

Congress did not pass new language and try to make it retroactive. It simply re-interpreted §1395bb by clearly stating JCAHO has had "Unique Deeming Authority." After § 125 is in effect, JCAHO and its accreditation decisions based upon its published regulatory standards

> ". . . may [be] . . . recognize[d] . . . upon such terms and conditions, and upon submission of such information, as the Secretary may require" (H.R. 6331, § 125 (c)).

Texas also accepts accreditation in lieu of State inspection and certification (Health and Safety Code,

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[24] Lisa Sprague, Hospital Oversight in Medicare: Accreditation and Deeming Authority, National Health Policy Forum, NHPF Issue Brief No. 802/May 6, 2005, p. 4.

§ 222.024), making JCAHO standards Texas hospital law for JCAHO-accredited hospitals. When they submit to the jurisdiction of JCAHO, hospitals bind themselves to follow relevant JCAHO policies as a matter of federal and Texas law.

Judicial recognition that JCAHO standards govern hospitals, starting with correcting the underlying legal mistake in *Poliner*, will reverse the trend of peer-review cases decided under HCQIA. Badfaith or economically motivated peer review, and flimsy findings of substandard care by the targeted peer-reviewed physicians, no longer can support judgments based on the presumed "objective reasonableness" of peer-review actions. From now on HCQIA's fairness and due process requirements for peer-review procedures and peer-review actions must be read in the context of JCAHO credentialing standards viewed as controlling law. CAMH requires all decisions on physicians' privileges to be uniform, fair, and directly related to patient care.[25]

This gross legal error can be corrected judicially. HCQIA is well-written and well-intended, but 20 years of misinterpretations reversed the intended effects, starting with the majority's opinion in *Austin v. McNamara*, above. Judge Pregerson, the dissenter in *Austin*, got it right:

> Section 11112 (a) reflects Congress's intent 'to encourage goodfaith professional review activities of healthcare entities'" (979 F.2d at 741).

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[25] CAMH 2000, MS.5.4.4, e.g., provides that "Decisions on reappointments or on revocation, revision, or renewal of clinical privileges must consider criteria that are directly related to the quality of care."

Once courts acknowledge that JCAHO standards pervade and inform HCQIA, SSI will have no quarrel with HCQIA's language, presumptions of immunity, or due process limitations. HCQIA was not intended to immunize badfaith, malicious or economically motivated peer-review. HCQIA should be interpreted so that JCAHO physician appointment, reappointment, clinical privileging, and peer-review action requirements inform all relevant parts of HCQIA.

Now that Congress declared when it passed HR 6331, that JCAHO standards govern all hospital actions pertaining to physicians, it appears entirely appropriate for this Court to correct this error that results in so many patients dying unnecessarily and healthcare costs rising. Good public policy can be made simply by interpreting a statute as Congress intended.

There is no need to amend. SSI believes HCQIA was intended to be read parallel with JCAHO standards. When the bill was debated in the mid-1980s, JCAHO standards were the prevailing hospital and physicians' standards and protections, and it was well known that JCAHO accreditation and credentialing standards and policies were updated every year. Nothing in HCQIA says it was to be frozen in time and interpreted separately from the continually evolving JCAHO standards.

It is unfortunate Congress acted too late to have these legal realities presented and argued before the Fifth Circuit. Neither counsel nor the deciding court was aware of Congress' then-recent actions.

Amicus SSI respectfully prays that this Court grants Certiorari and interprets HCQIA so physicians can trust they have enforceable due process

rights to sustain the independence and free speech protections they need to advocate for patients and make healthcare better, safer, and cheaper.

Respectfully submitted,

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APPENDIX

APPENDIX A

The "White Coat" of Silence

LET'S CONSIDER A SCENARIO, that may or may not be hypothetical—that will be for you to decide. In an unnamed hospital, a newly appointed Chief Nursing Officer (CNO) is hired as a change agent, or at least that is what she is told by the hospital's Chief Executive Officer (CEO) and several Vice Presidents. As a first order of business, the CNO begins to document problem areas at the hospital. The list includes a director of Nursing (DON) WHO prevaricates, especially when it comes to defining staffing needs; abandonment of duty by some nurses in the chain of command; a nurse who continues to make medication administration errors; the failure of the computerized charting system to perform as expected; and other problems of the same importance.

When verbal reports to a superior fall on deaf ears and generate responses such as "the DON is doing what she can," the CNO decides to write a detailed memo outlining the problems and her recommendations. A copy of the CNO's report the is given to the CEO and all department VP'S including the CNO's direct superior. One would expect that hospital administration would show appropriate concern for the severity of the documented deficiencies and pain for immediate corrective action. However, this is a management-impaired hospital and following the unspoken rule of the hospital following the unspoken rule of "killing the messenger," the CNO is sacrificed for failing to adhere to another unspoken rule of the hospital

By Geneviève M. Clavreul, RN, PhD.

Hospitals, like police departments and other institutions, have their own codes of silence to protect against human error—no malice, no ill intent, no nefarious plan—just plain old human error.

and nursing administration, which is "bring us no bad news."

For many, the above example will have the ring of truth, because this situation exists in their hospital today, or in the past. There will be others who say their hospital would never tolerate such a practice. But the above does put a spotlight on what I have come to call the "White Coat of Silence."

Hospitals, like police departments and other institutions, have their own codes of silence. This code was established to give a person some protection from the consequences of what is often just human error—no malice, no ill intent, no nefarious plan—just plain old human error. However, as in police work, there are times when the white coat of silence is extended to cover the mistakes of a person who is incompetent or unethical. When this happens, the healthcare community violates its trust with the public it serves and bad outcomes follow.

The cloak of privacy offered by quality improvement projects should not be confused with the white coat of silence. The shield of privacy is invoked to allow the hospital staff to freely and fully investigate a medical or nursing mishap or error. This shield is offered under the theory that privacy assurance will allow the nurse or doctor, without fear of retribution and accusation, to discuss the mistake that occurred. This does not mean that the nurse or doctor responsible is free from consequence if an event is deemed caused by negligence or poor care.

An effective quality improvement process leads to an environment where patient rights and care are placed at the forefront without relegating the nursing and medical staff to second-class status. The white coat, on the hand, places emphasis on protecting the nursing and medical staff first and encourages an environment where patient rights and care are not the core focus of the healthcare team.

The white coat flourishes in an environment where hospital administration and nursing management in particular, is viewed as hostile towards good nursing practice. This insidious code creeps into a hospital as a defense against what is viewed by employees as an administration that is unresponsive and often retaliatory.

Through society may reward the whistle blower for calling attention to malfeasance, safety issues, and, in the case of nursing, poor or negligent patient care--the reality is that the administration, and in some cases the nursing team itself, does not support the nurse who is a whistle blower. It is an unfortunate occurrence within nursing, and it doesn't have to be this way.

I was having lunch with a nurse whom I had known and worked with many years ago. Catching up on old times we chatted about the numerous experiences and frustrations our many years of nursing had brought us. She shared with me an experience she had one night many years ago at one of Los Angeles finest hospitals.

She and five other nurses, a tech, and two doctors were preparing to move a patient into surgery. The need for surgery was immediate and urgent, and as they prepared the patient one of the doctors handed

her a pre-filled syringe and ordered that she administer it to the patient. Since she did not draw the medication and, therefore, did not know what was in the syringe she asked the doctor what the syringe contained. He refused to tell her, stating instead that without it the patient would suffer ill effects and that she had t administer it.

Of course she refused, and stated that the physician should administer it instead. He refused and then ordered one of the other nurses to do it. After much haranguing and brow beating one of the other nurses acquiesced and administered the injection of the mystery drug. Afterwards, she reported the occurrence to nursing service; each of the other five nurses confirmed her story and supported her complaint. But the tech and the mystery syringe doctor both developed amnesia. Shortly after the complaint, the six nurses began to find themselves pressured t find other employment–the white coat of silence strikes again.

A reasonable person might have thought that the doctor who insisted that the nurse administer an unidentified drug would have been the one to be made to suffer for his unprofessional and possibly dangerous actions, but cf course, hospital management is not always known for reasonable behavior.

What happened to my friend and the other nurses is the byproduct of poor and weak management, not an uncommon occurrence in the hospital setting.

All too often a nurse who makes a complaint about another nurse or doctor is made to weigh in advance the possible repercussions to herself. Often the act of reporting their suspicions to the charge nurse or head nurse is enough to mark the nurse as a troublemaker

and thus, a potential victim of kill the messenger syndrome. Poor managers often feel threatened by the nurse who steps forward, especially if the nurse being reported is perceived by nursing management as a hard worker.

The weak manager often confuses the nurse who is willing to work any and all shifts, multiple days, fetch coffee, run errands, with being a nurse, when in reality this nurse is usually a sycophant who is undermining the esprit de corps. A consequence of the sycophant's behavior is that the manager often rewards them for being a teacher's pet while the very real concern of the whistle blower is ignored and the whistle blower is the one who is punished. It only takes one or two negative consequences before the nursing staff gets the message. Good nurses start updating their resume or, worse, stop caring.

Does the white coat have no rule nursing practice in our hospitals? Of course not! Most nurses abhor the thought of poor nursing care being hidden, yet feel totally helpless to do anything about it for fear of losing their job or, worse yet, their license.

The white coat thrives in two environments: where there is

Reporting suspicions to the charge nurse is often enough to get marked as a troublemaker and potential victim of the kill the messenger syndrome.

poor or weak nursing management that does not advocate for patients and nurses, and where nurses fail to support the whistle blower.

Changing this work environment is not impossible. When nurses work together to define and enforce the highest standards of nursing practice then nursing

management has little choice but to respond. They learn that nurses demand leaders to show backbone. Mediocre nurses quickly change their behavior or move on when they realize that their obsequious and sycophantic behavior is unrewarded. Floor nurses can have a dramatic effect on who the hospital administration appoints as the CNO, and ultimately on who the CNO appoints as DON, who the DON appoints a s Head Nurse, and so on.

THE WHITE COAT OF SILENCE IS NURSING'S DIRTY LITTLE SECRET. It can only thrive in an environment that is permissive and unresponsive. If you know that you are working in a hospital where the "white coat of silence" is the rule and not the exception, there are some steps you can take to protect your patients and yourself.

FIRST AND FOREMOST, always document. Although documenting can be time consuming, it is important to create a paper trail.

SECOND, become thoroughly familiar with your hospital's quality improvement protocol and employee discipline process.

THIRD, when reporting unsafe nursing practices, sentential events, possible errors, and so on, always follow the chain of command and keep a copy of the documentation that you submitted.

FOURTH, if the situation worsens, or you begin getting the feeling that you are working around with a "target on your back," give serious consideration to looking for a position in another hospital.

It may seem extreme to change jobs when confronted with the white coat but it's not. If you are working in a hospital where the norm is to ignore real and valid

concerns about safe nursing practice and good patient care you cannot personally solve a system-wide problem. What you can do, however, is to provide the documentation that administration was informed, but that they chose to remain ignorant of the problems. Why? Because when the hospital suffers an event big enough—if it tolerates a white code of silence, it eventually will—then it won't be able to hide its practices.

Then your documentation can be used to instigate change.

Genevieve M. Clavreul is a health care manage-ment consultant. She is an RN and has experience as a director of nursing and as a teacher of nursing management. She can be reached at: Solutions Outside the Box; PO Box 867, Pasadena, CA; gmc@solutionsoutsidethebox.net; 626-844-7812.

THIS ARTICLE IS ARCHIEVED ON LINE.

http://www.solutionsoutsidethebox.net/documents/2005/White%20Coat%20of%20Silence.pdf

The 'White Coat' of Silence: Working Nurse Feb 21, 2005 pages: 11-15.

APPENDIX B

FOR IMMEDIATE RELEASE
January 26, 2005

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New Study Finds U.S. Hospitals Must Improve Workplace Communication to Reduce Medical Errors, Enhance Quality of Care

Expert Panel Issues Call-to-Action with New National Standards and Training Recommendations

WASHINGTON—January 26, 2005—According to findings from a study released today in a national briefing of healthcare stakeholders, the prevalent culture of poor communication and collaboration among health professionals relates significantly to continued medical errors and staff turnover. Additionally, a lack of adequate support systems, skills and personal accountability results in communication gaps that can cause harm to patients.

A national study of more than 1,700 nurses, physicians, clinical-care staff and administrators found that fewer than 10 percent address behavior by colleagues that routinely includes trouble following directions, poor clinical judgment or taking dangerous shortcuts. In all, the study pinpoints seven categories of problems that are frequently encountered, yet rarely addressed. The study was co-sponsored by the American Association of Critical-Care Nurses (AACN) and VitalSmarts, a company specializing in leadership training and organizational performance.

"This research validates what our 100,000 constituents have communicated to us as the number one barrier hindering optimal care for patients," said

Kathy McCauley, RN, PhD, BC, FAAN, FAHA, president, AACN. "Too often, improving workplace communication is seen as a 'soft' issue—the truth is we must build environments that support and demand greater candor among staff if we are to make a demonstrable impact on patient safety."

To drive the cultural transformation needed to improve communication in hospitals, AACN unveiled today a set of national standards to promote skilled communication and collaboration among nurses and other caregivers. The AACN standards and VitalSmarts recommendations emphasize the urgent need for hospitals to implement initiatives, especially communication training and education, to ensure that healthcare professionals deliver safe, high quality care to their patients.

AACN and VitalSmarts combined their resources to better understand communication problems in hospitals through the survey *Silence Kills: The Seven Crucial Conversations for Healthcare*. Among the study's key findings:

> 84 percent of physicians and 62 percent of nurses and other clinical-care providers have seen coworkers taking shortcuts that could be dangerous to patients.
>
> 88 percent of physicians and 48 percent of nurses and other providers work with people who show poor clinical judgment.
>
> Fewer than 10 percent of physicians, nurses and other clinical staff directly confront their colleagues about their concerns, and one in five physicians said they have seen harm come to patients as a result.

> The 10 percent of healthcare workers who raise these crucial concerns observe better patient outcomes, work harder, are more satisfied and are more committed to staying in their jobs.

"People frequently see these problems, but too often they fail to talk about them," says Joseph Grenny, president of VitalSmarts and co-author of VitalSmarts' *New York Times* best-selling books *Crucial Conversations and Crucial Confrontations*. "Healthcare professionals who embrace the findings of this study and start talking candidly and safely about these seven problems will find that outcomes can improve dramatically."

According to panelist Dennis S. O'Leary, MD, president of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), communication is a top contributor to medical errors in healthcare facilities. "The standards and recommendations put forth today make an important contribution to beginning to solve the identified communication problems," said Dr. O'Leary.

Panelist Karlene Kerfoot, RN, PhD, CNAA, FAAN, senior vice president for patient care services and chief nurse executive at Clarian Health Partners in Indianapolis, explained that by focusing on workplace communication improvements, Clarian has experienced greater recruitment and retention success and improved safety overall.

"Nurses must be as proficient at handling personal communication as they are in clinical skills," said Connie Barden, RN, MSN, CCNS, CCRN, executive editor of *AACN's Standards for Establishing and Sustaining Healthy Work Environments: A Journey* to

Excellence. "According to the Standards, a culture of safety and excellence requires that individual nurses and healthcare organizations make it a priority to develop communication skills that are on par with expert clinical skills."

# # #

For copies of the Silence Kills study report and the *AACN Standards for Establishing and Sustaining Healthy Work Environments*, visit http://www.rxforbettercare.org.

With 100,000 members and constituents, the American Association of Critical-Care Nurses is the largest specialty nursing organization in the world. Its headquarters are located in Aliso Viejo, Calif. Founded in 1969, the association has more than 240 chapters in the U.S. and abroad and is working toward a healthcare system driven by the needs of patients and their families, where critical care nurses make their optimal contribution. Complete information about AACN is available at http://www.aacn.org.

A world leader in leadership training and organizational performance, VitalSmarts. (http://www.vitalsmarts.com) *provides products and services to hundreds of companies, including over 300 of the Fortune 500. For over twenty-five years, and with over 20,000 participants, the company principals have researched methods for bringing about systematic and lasting change.*

APPENDIX C

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DEATH RATE 70% LOWER AT NATION'S TOP-RATED HOSPITALS: HEALTHGRADES 11th ANNUAL HOSPITAL QUALITY STUDY

—The Most Comprehensive Annual Study of Hospital Quality in America Examines 41 Million Patient Records at 5, 000 Hospitals Over Three Years; Mortality Rates Improve Nationally—

—City and State-Level Hospital Death Rates Released—

—Hospital Quality Ratings Available Free to Consumers at HealthGrades.com—

GOLDEN, Colo. (October 14, 2008)—Patients have on average a 70 percent lower chance of dying at the nation's top-rated hospitals compared with the lowest-rated hospitals across 17 procedures and conditions analyzed in the eleventh annual *Health Grades Hospital Quality in America Study*, issued today by HealthGrades, the leading independent healthcare ratings organization.

While overall death rates declined from 2005 to 2007, the nation's best-performing hospitals were able to reduce their death rates at a much faster rate than poorly performing hospitals, resulting in large state, regional and hospital-to-hospital variations in the quality of patient care, the study found.

HealthGrades Hospital Quality in America Study, also found that if all hospitals performed at the level of five-star rated hospitals, 237,420 Medicare dealths could potentially have been prevented over the three years studied. More than half of those deaths were associated with four conditions: sepsis (a life-threatening illness caused by systemic response to infection), pneumonia, heart failure and respiratory failure.

The HealthGrades study of patient outcomes at the nation's approximately 5,000 hospitals is the most comprehensive annual study of its kind, analyzing more than 41 million Medicare hospitalization records from 2005 to 2007. The study examines procedures and conditions ranging from heart valve-replacement surgery to heart attack to pneumonia.

Based on the study, HealthGrades today made available its 2009 quality ratings for all nonfederal hospitals in the country at www.healthgrades.com, a Web site designed to help individuals research and compare local healthcare providers.

Full reports on death rate trends in each of the 50 states and the District of Columbia are available in the study. And, for the first time, HealthGrades has released hospital death rates for the nation's 15 largest metropolitan statistical areas: New York, Los Angeles, Chicago, Dallas, Philadelphia, Houston, Miami, Washington D.C., Atlanta, Boston, Detroit, San Francisco, Phoenix, Riverside-Inland Empire (CA) and Seattle. Large variation exists between major metropolitan areas.

"Geography should not be a major factor in patients' outcomes. If our nation's hospitals are to close the quality gap and guarantee an equally high level of

medical care for every patient, no matter where he or she lives, it will require a commitment by our nation and its communities to demand more from quality improvement," said Samantha Collier, MD, HealthGrades' chief medical officer and a study author. "Until then, it is imperative that anyone seeking medical care at a hospital do their homework and know the hospital's quality ratings before they check in."

The study's major findings are:

> The nation's inhospital risk-adjusted mortality rate improved, on average, 14.17 percent from 2005 to 2007, but the degree of improvement varied widely by procedure and diagnosis studied (range: 6.30% to 20.94%). Five star-rated hospitals' mortality rates continue to improve at a faster rate (13.18%) than 1- or 3-star hospitals (12.30% and 13.14%, respectively).
>
> Large gaps persist between the "best" and the "worst" hospitals across all procedures and diagnoses studied. Five star-rated hospitals had significantly lower risk-adjusted mortality across all three years studied. Across all procedures and diagnoses studied, there was an approximate 70 percent lower chance of dying in a 5-star rated hospital compared to a 1-star rated hospital. Across all procedures and diagnoses studied, there was an approximate 50 percent lower chance of dying in a 5-star rated hospital compared to the U.S. hospital average.
>
> If all hospitals performed at the level of a 5-star rated hospital across the 17 procedures and diagnoses studied, 237,420 Medicare lives

could have potentially been saved from 2005 to 2007.

Fifty-four percent (128,749) of the potentially preventable deaths were associated with just four diagnoses: Sepsis, heart failure, pneumonia and respiratory failure.

Variation in risk-adjusted mortality exists not only at the national level but also at the state and regional levels. The greatest quality differences between states occurred in hospital death rates for heart failure, pulmonary, stroke and cardiac surgery.

The region with the lowest overall risk-adjusted mortality rates was the East North Central region (IL, IN, MI, OH, and WI), while the East South Central region (AL, KY, MS, and TN) had the highest mortality rates.

The East North Central region (IL, IN, MI, OH, and WI), had the highest percentage of best-performing hospitals at 26 percent. Less than seven percent of hospitals within the New England region (CT, MA, ME, NH, RI, and VT) were top-performing hospitals.

In the study's analysis of hospital death rates, the following 17 procedures and conditions were analyzed: bowel obstruction, chronic obstructive pulmonary disease, coronary bypass surgery, coronary interventional procedures (angioplasty/stent), diabetic acidosis and coma, gastrointestinal bleed, gastrointestinal surgeries and procedures, heart attack, heart failure, pancreatitis, pneumonia, pulmonary embolism, resection/replacement of the abdominal aorta, respiratory failure, sepsis, stroke, and valve replacement surgery. The full study, along with its

methodology and state-by-state hospital-quality statistics, can be found at www.healthgrades.com.

HealthGrades' Star Ratings of Hospitals

On its Web site, HealthGrades offers, free to consumers, quality ratings of 27 procedures and treatments for every nonfederal hospital in the country. The Web site is designed so that consumers can easily compare patient outcomes at their local hospitals for procedures ranging from aortic aneurysm repair to bypass surgery. Each hospital receives a star rating based on its patient outcomes in terms of mortality or complication rates for each procedure or treatment. Hospitals with outcomes that are above average to a statistically significant degree receive a five-star rating. Hospitals with average outcomes receive a three-star rating, and hospitals with outcomes that are below average receive a one-star rating. Because no two hospitals or their patients' risk profiles are alike, HealthGrades employs extensive risk-adjustment algorithms to ensure that it is making fair *comparisons.*

About Health Grades

Health Grades, Inc. (Nasdaq: HGRD) is the leading healthcare ratings organization, providing ratings and profiles of hospitals, nursing homes and physicians. Millions of consumers and many of the nation's largest employers, health plans and hospitals rely on HealthGrades' independent ratings, advisory services and decision-support resources to make healthcare decisions based on the quality and cost of care. More information on the company can be found at www.healthgrades.com.

APPENDIX D

In the Literature

FIVE YEARS AFTER TO *ERR IS HUMAN*: WHAT HAVE WE LEARNED?

Five years ago, the Institute of Medicine (IOM) issued its landmark report on medical errors, *To Err Is Human: Building a Safer Health System*. The report's finding that as many as 98,000 people die each year due to medical errors ignited professional and public dialogue. Patient safety has since become a frequent topic for journalists, health care leaders, and consumers, but is health care any safer now? And if not, why not?

Two authors of the IOM report, Lucian Leape, M.D., of the Harvard School of Public Health, and Donald Berwick, M.D., of the Institute for Healthcare Improvement, endeavor to answer these questions in "Five Years After To Err Is Human: What Have We Learned?" (*Journal of the American Medical Association*, May 18, 2005). Despite finding small improvements at the margins—fewer patients dying from accidental injection of potassium chloride, reduced infections in hospitals due to tightened infection control procedures—it is harder to see the overall, national impact, Leape and Berwick say. "[T]he groundwork for improving safety has been laid in these past five years but progress is frustratingly slow," they write.

Accomplishments

While *To Err Is Human* has not yet succeeded in creating comprehensive, nationwide improvements, it has made a profound impact on attitudes and organizations. First, it has changed the way health care

professionals think and talk about medical errors and injury, with few left doubting that preventable medical injuries are a serious problem. "It truly changed the conversation," say Leape and Berwick. A central concept of the report—that bad systems and not bad people lead to most errors—has since become a mantra in health care.

The second major effect of the report was that it helped recruit a broad array of stakeholders to advance the cause of patient safety. In 2001, Congress responded to the IOM recommendations by allocating $50 million annually for patient safety research to the Agency for Healthcare Research and Quality (AHRQ), the lead federal agency for health care safety. Other important players that have emerged include the Veteran's Health Administration, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the Centers for Medicare and Medicaid Services (CMS), as well as purchasers and payers. However, the most important stakeholders, say the authors, are the physicians, nurses, therapists, and pharmacists who have become much more alert to safety hazards and who are committed to making improvements on the front lines.

Clearly, the report has also produced real changes in the practice of health care. In 2003, JCAHO began requiring hospitals to implement 11 safety practices, including improving patient identification, communication, and "surgical site verification" (marking a body part to ensure surgery is performed on the correct part). More safe practices will be added in 2005. In addition, teaching hospitals initiated new residency training hour limitations in 2003, aimed at reducing errors due to fatigue.

Challenges

With all this growing awareness and activity, why is health care not measurably safer? The answers, the authors say, lie in the very culture of medicine. Creating a culture of safety requires changes that physicians may perceive as threats to their autonomy and authority. Fear of malpractice liability, moreover, may create an unwillingness to discuss or even admit to errors. Other issues include the complexity of the health care industry, with its vast array of specialties, subspecialties, and allied health professionals; a lack of leadership at the hospital and health plan level; and a scarcity of measures with which to gauge progress.

The current reimbursement system can also work against safety improvement and, in some cases, may actually reward less-safe care, the authors say. For instance, some insurance companies will not pay for new practices to reduce errors, while physicians and hospitals can bill for additional services that are needed when patients are injured by mistakes.

Next Steps

Despite formidable barriers, the authors expect to see dramatic advances in the next five years in the following areas: implementation of electronic health records, wide diffusion of proven and safe practices, spread of training on teamwork and safety, and full disclosure to patients following injury. However, while these advances will have an impact on reducing errors, they represent only a small fraction of the work that needs to be done. To create comprehensive, nationwide change, pressure must be applied to the health care industry. Public outrage, reformed reimbursement policies, and regulation can create some of

this needed pressure. In addition, the authors suggest payment incentives to accelerate widespread adoption. It may be equally important, they say, to create negative financial consequences for hospitals or organizations that continue to perform unsafe practices.

The single most important step, however, is to set and adhere to "strict, ambitious, quantitative, and well-tracked national goals," say Leape and Berwick. They urge AHRQ to bring together organizations, including JCAHO, CMS, and the American Medical Association, to agree to a set of patient safety goals to be reached by 2010. The most important lesson of the past five years, the authors argue, is that "we will not become safe until we choose to become safe."

Clinical Effectiveness of Safe Practices

Intervention	Results
Physician computer order entry	81 % reduction of medication errors[a,b]
Pharmacist rounding with team	66% reduction of preventable adverse drug events[c]
	78% reduction of preventable adverse drug events[d]
Rapid response teams	Cardiac arrests decreased by 15%[e]
Team training in labor and delivery	50% reduction in adverse outcomes in preterm deliveries[f]
Reconciling medication practices upon hospital discharge	90% reduction in medication errors[g]

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[a] D. W. Bates, J. M. Teich, J. Lee et al., "The Impact of Computerized Physician Order Entry on Medication Error Prevention," Journal of the American Medical Informatics Association 6 (July/August 1999): 313-21.

[b] D. W. Bates and A. A. Gawande, "Improving Safety with Information Technology," New England Journal of Medicine 348 (June 19, 2003): 2526-34.

[c] L. L. Leape, D. J. Cullen, M. D. Clapp et al, "Pharmacist Participation on Physician Rounds and Adverse Drug Events in the Intensive Care Unit," Journal of the American Medical Association 282 (July 21, 1999): 267-70.

[d] S. N. Kucukarslan, M. Peters, M. Mlynarek, D. A. Nafziger, "Pharmacists on Rounding Teams Reduce Preventable Adverse Drug Events in Hospital General Medicine Units," Archives of Internal Medicine 163 (September 22, 2003): 2014-18.

[e] L. Landro, "The Informed Patient: Hospitals Form 'SWAT' Teams to Avert Deaths," Wall Street Journal, December 1, 2004.

[f] B. Sachs, Beth Israel Deaconess Medical Center, written communication, October 2004.

[g] J. D. Rozich and R. K. Resar, "Medication Safety: One Organization's Approach to the Challenge," Journal of Clinical Outcomes Management 8 (October 2001): 27-34.

Ventilator bundle protocol	Ventilator-associated pneumonias decreased[h]

[h] J. Whittington, written communication, March 2005.

Source: L. L. Leape and D. M. Berwick, "Five Years After To Err Is Human: What Have We Learned?" Journal of the American Medical Association 293 (May 18, 2005): 2384-90.

APPENDIX E

Joint Commission Forms National Task Force
To Review Relevance of Standards,
Compliance Requirements

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(Oakbrook Terrace, Ill.—April 30, 2001) The Joint Commission on Accreditation of Healthcare Organizations today launched a sweeping review of its hospital standards and requirements for demonstrating compliance with standards.

An 18-member task force will pinpoint which accreditation standards are most relevant to the safety and quality of patient care, and target for elimination or modification those standards that do not contribute to good patient outcomes. In addition, the task force will identify redundant and overly burdensome documentation requirements for potential streamlining, and identify areas needing additional focus.

The project is part of a concerted effort by the Joint Commission to enhance the value and effectiveness of its accreditation process. The initiative will identify opportunities to streamline compliance activities for the nearly 5,000 accredited hospitals, allowing the organizations to pursue their efforts on improving patient care. The Joint Commission plans to conduct similar reviews for its seven other accreditation programs in the near future.

"Accreditation is about performance that directly impacts patient care and safety, not process and paperwork," says Charles A. Mowll, executive vice president, Joint Commission. "We want Joint Commission accreditation to continue to offer measurable benefits to hospitals and the patients they serve. A thorough, comprehensive assessment is crucial to ensure that Joint Commission standards accurately reflect the dynamic environment of health care today." Only a few recently established standards—such as groundbreaking requirements regarding pain management, patient safety and restraint and seclusion—are exempt from scrutiny. These standards have already been subject to the type of broad consensus-building efforts that the Joint Commission is now seeking for older requirements.

In addition, standards relating directly to Medicare Conditions of Participation (CoPs) for hospitals will receive special consideration. While the task force will identify potential additions, deletions or modifications to this subset of standards, the Joint Commission recognizes that these standards are the "law of the land" and are required for Medicare deeming. The task force's ideas, however, may potentially serve as the basis for Joint Commission discussions with the Health Care Financing Administration as changes are considered to CoPs.

Led by Ken Shull of the South Carolina Hospital Association, the task force will include quality directors, medical records directors, nurses, physicians, engineers, risk managers and other hospital leaders who have first-hand experience with Joint Commission accreditation standards and surveys. Furthermore, physician groups will be enlisted to specifically review medical staff standards.

"Many hospitals are faced with limited financial revenues, a national staffing crisis and an ever-increasing burden of compliance demands imposed by state and federal regulators, accreditors and managed care organizations," Shull says. "I welcome this invitation to work with my task force colleagues and the Joint Commission to offer constructive input on what most directly impacts patient care."

Specifically, the task force will consider the following criteria in reviewing standards:

> Continuing relevance in promoting patient safety or high quality care.
>
> Redundancy with other external quality requirements.
>
> Applicability of standards to hospital care.
>
> Likelihood that compliance will be consistently evaluated.
>
> Extent to which compliance can actually be measured.
>
> Linkage to patient outcomes.

The Joint Commission also will ask the task force to identify common misconceptions and misinformation regarding requirements for demonstrating standards compliance. These fallacies often result in unnecessary costs for hospitals in both staff time and resources.

In addition to the comprehensive standards review, the Joint Commission has in recent years made a number of significant changes intended to enhance the evaluation of critical patient safety and patient care functions and to achieve an accreditation process that remains consultative and centered on perform-

ance improvement. A redesigned on-site survey process now focuses more on individual-centered evaluations and allows more time for observation in patient care units. In addition, the Joint Commission is conducting pilot testing of a proposed model to assess staffing effectiveness and a more continuous survey process.

http://www.jcaho.org/news/nb324.html

APPENDIX F

The Joint Commission

Behaviors that Undermine a Culture of Safety

http://www.jointcommission.org/NewsRoom/PressKits/Behaviors+that+Undermine+a+Culture+of+Safety/app_stds.htm

Issue 40: July 9, 2008

Applicable Joint Commission Standards

Standard LD.03.01.01
Rationale for LD.03.01.01

Leaders create and maintain a culture of safety and quality throughout the [organization]. Safety and quality thrive in an environment that supports teamwork and respect for other people, regardless of their position in the [organization]. Leaders demonstrate their commitment to quality and set expectations for those who work in the [organization]. Leaders evaluate the culture on a regular basis. Leaders encourage teamwork and create structures, processes, and programs that allow this positive culture to flourish. Disruptive behavior that intimidates others and affects morale or staff turnover can be harmful to [patient] care. Leaders must address disruptive behavior of individuals working at all levels of the [organization], including management, clinical and administrative staff, licensed independent practitioners, and governing body members.

Elements of Performance for LD.03.01.01

1. Leaders regularly evaluate the culture of safety and quality using valid and reliable tools.

2. Leaders prioritize and implement changes identified by the evaluation.
3. Leaders provide opportunities for all individuals who work in the hospital to participate in safety and quality initiatives.
4. The hospital has a code of conduct that defines acceptable, disruptive, and inappropriate behaviors.
5. Leaders create and implement a process for managing disruptive and inappropriate behaviors.
6. Leaders provide education that focuses on safety and quality for all individuals. (See also LD.04.04.05, EP 6)
7. Leaders establish a team approach among all staff at all levels.
8. All individuals who work in the hospital, including staff and licensed independent practitioners, are able to openly discuss issues of safety and quality.
9. Literature and advisories relevant to patient safety are available to all individuals who work in the hospital.
10. Leaders define how members of the population(s) served can help identify and manage issues of safety and quality within the hospital.

Medical Staff Standard
MS.4.00

Overview

Determining the competency of practitioners to provide high quality, safe patient care is one of the most

important and difficult decisions an organization must make. The development and maintenance of a credible process to determine competency requires not only diligent data collection and evaluation, but also the actions by both the governing body and organized medical staff.

The credentialing and privileging process involves a series of activities designed to collect, verify, and evaluate data relevant to a practitioner's professional performance. These activities serve as the foundation for objective, evidence-based decisions regarding appointment to membership on the medical staff, and recommendations to grant or deny initial and renewed privileges. In the course of the credentialing and privileging process, an overview of each and privileging process, an overview of each applicant's licensure, education, training, current competence, and physical ability to discharge patient care responsibilities is established.

Three new concepts are introduced in the revised credentialing and privileging standards. First, the revised credentialing and privileging standards have been informed throughout by the six standards have been informed throughout by the six areas of "General competencies" developed by the accreditation council for graduate medical education Education (ACGME) and the American Board of Medical Specialties (ABMS) joint initiative. The areas of general competencies include the following:

Patient Care

Medical/Clinical Knowledge

Practice-based Learning and Improvement

Interpersonal and Communication Skills

Professionalism

Systems-based Practice.

Integrating these concepts into the standards allows the organized medical staff to expand to a standards allows the organized medical staff to expand to a more comprehensive evaluation of a practitioner's professional practice.

APPENDIX G

Swinging Pendulum of Peer Review Immunity

By Charles I. Artz, Esq.
Physician's News Digest—Published November 2001
http://www.physiciansnews.com/law/1101.html

Recent appellate court decisions in Pennsylvania and other jurisdictions raise the question whether the immunity afforded hospitals and reviewers under the federal Health Care Quality Improvement Act (HCQIA) have allowed the peer review system to be improperly utilized, or even abused in some cases.

HCQIA was enacted by Congress in 1996 to provide immunity against civil litigation damages for physicians and hospitals engaging in professional peer review, and to restrict the ability of incompetent physicians to move from state to state without disclosure or discovery of prior damaging or incompetent medical performance. Immunity under HCQIA can be established if the peer review process meets four general standards:

> It had an objective, reasonable belief that its action furthered quality health care.
>
> It made an objective, reasonable effort to obtain the facts.
>
> Under the *totality of the circumstances*, the physician being reviewed received adequate notice and hearing (i.e., due process) procedures.
>
> The organization had a reasonable belief that its actions were warranted.

Superficial review of this four-part test suggests physicians should receive due process throughout the

entire peer review, and serious quality of care issues must exist before a physician's privileges can be suspended, reduced or revoked. Case law and experience demonstrate the contrary.

Bias and Conflicts of Interest Immaterial

In *Manzetti v. Mercy Hospital of Pittsburgh*, the Pennsylvania Supreme Court held on July 18, 2001 that the hospital and reviewers were entitled to immunity under HCQIA. The Supreme Court disregarded all evidence relating to the reviewed physician's competitors' involvement in the case and attacks against hi m. The Court stated that any self-interest, bias or conflicts of interests by the reviewers were *immaterial*. According to the Court, the only time HCQIA precludes an economic competitor from involvement in the internal peer review process is at the hearing panel phase of the case; however, HCQIA does not preclude economic competitors from perpetrating due process violations and inculcating bias throughout the early phases of the review process. Under most hospital bylaws, by the time the physician gets to the fair hearing panel, the burden has shifted against the physician with the requirement that the physician prove by clear and convincing evidence that all prior decisions were arbitrary and capricious or factually baseless. Practical experience demonstrates this is a virtually impossible burden to sustain and standard to satisfy.

The Supreme Court also held that the "reasonable effort" prong of the four-part HCQIA immunity test is satisfied if the review activities are "sensible," but they do not have to be "flawless." Thus, the Supreme Court has countenanced due process violations and errors in the peer review process.

Sloppy, Negligent and Wrong Peer Review Warrants Immunity

In *Donnell v. HCA Health Services of Kansas, Inc.*, the Kansas Court of Appeals held on July 6, 2001 that physician peer reviewers are immune from liability under HCQIA even if their investigations are *sloppy, negligent, and wrong*. Physicians must prove bad faith and malice to have a peer review decision overturned.

This decision, like *Manzetti* above, allows a hospital to make serious mistakes about the quality of a physician's health care. It also permits termination of the physician's staff privileges, and the detrimental effect of a Data Bank entry, all with immunity from liability and practical impunity.

One Mistake and Done: Free Ride for Abuse

In Meyer v. Sunrise Hospital, the Nevada Supreme Court held on May 15, 2001 that a hospital's decision to terminate a physician based upon a single incident, regardless of the high quality of care the physician provided throughout the remainder of his career, was sufficient to protect the hospital under HCQIA's immunity provisions.

One Justice on the Supreme Court recognized the unfairness of the statute, but was compelled to uphold the decision. The Justice noted that HCQIA can sometimes be used, "not to improve the quality of medical care, but to leave a doctor who was unfairly treated without any viable remedy." That Justice also stated: "basically as long as the hospitals provide procedural due process and state some minimal basis related to quality health care, whether legitimate or not, they are immune from liability, which leaves the

hospitals free to abuse the process for their own purposes."

No Constitutional Infractions

In *Freilich v. Board of Directors of Upper Chesapeake Health, Inc.*, a federal court in Maryland held on May 14, 2001 that the HCQIA immunity provisions do not violate due process or equal protection under the U.S. Constitution.

Review Must Be 100% Wrong?

In *Brader v. Allegheny General Hospital*, 167 F.3d 832 (3rd Cir. 1999), it was proven that the hospital's outside expert report had several incorrect conclusions. The Court of Appeals, however, ignored these mistakes because it found the report to be "otherwise thorough." The Court implied that the expert report must be entirely mistaken, and that the mistakes must be obvious. Because they were not, the hospital's decision was not unreasonable, and the first and fourth prongs of the HCQIA immunity test were satisfied.

Bias and Mistakes Early and Often Mean Nothing

In *Gordon v. Lewistown Hospital*, 714 A.2d 539 (Pa. Cmwlth. 1998), Commonwealth Court found that there is a presumption of validity of the hospital's disciplinary procedures. An outside consultant was retained. The Hearing Officer was an attorney, who was determined not to be in economic competition with the physician, but was a neutral party. Even though some of the physician's direct economic competitors were involved in the decision, and there was evidence of a history of hostility toward him, none of those individuals participated in drafting the outside report. The Court then looked to the *totality*

of the process leading to the professional review action. Under that broad test, even though some parts of the process were critically flawed and biased, the Court said, in totality, the physician got all the process he was due.

These cases are the latest in a series of decisions nationwide leaving physicians who are subjected to peer review without any legal remedies, and without any right to secure a fair hearing and a fair outcome.

The Dreaded Data Bank

An "adverse action" following peer review results in the hospital reporting (through the Medical Board) the physician to the National Practitioner Data Bank, commonly referred to as the "Data Bank." Many reports conclude physicians' care was "incompetent," "unprofessional" or other professionally disastrous terms. Economic experts have opined that such a negative statement in the Data Bank directly results in substantial economic loss to a physician. The Pennsylvania Supreme Court in *Hayes v. Mercy Health Corp.*, 559 Pa. 21, 739 A.2d 114 (1999) stated that a physician's Data Bank entry may, if left unchallenged, have a deleterious effect on the physician's medical career.

Money and Vengeance

The author has represented orthopedic surgeons, cardiologists, OB/GYNs, thoracic surgeons, anesthesiologists, ophthalmologists, family physicians, internists and other specialists in hospital peer review cases and medical staff privileges litigation. More often than not in the author's experience, peer review is initiated against a physician for one of three reasons: (1) by economic competitors for financial

reasons; (2) in retaliation against the physician for not "playing ball" in one manner or another (economic or otherwise); or (3) in retaliation for the physician raising concerns about other physicians' care and seeking to have those providers' outcomes reviewed. The state "whistleblower" law does not protect these physicians. The Pennsylvania Peer Review Protection Act, which allows physicians to litigate tort and contract breach claims in state court against hospitals whose peer review is effectuated by malice or bad faith, has been "trumped" (although not technically preempted) by the federal HCQIA immunity standards.

Shifting Sands

Hospital bylaws impose difficult legal standards and burdens on physicians. Typically, after a physician is the subject of an adverse recommendation or an adverse action by a medical executive committee, the physician is given a fair hearing. Traditional notions of fairness might lead one to believe that the hospital would have the burden of proof by at least a preponderance of the evidence to demonstrate the physician's quality of care was below some recognized and measurable standard warranting a quality of care concern. After al l, hospitals have a legitimate concern about corporate liability and "negligent credentialing" following the Supreme Court's *Nason Hospital* decision in 1991.

Absolutely every set of hospital bylaws the author has reviewed do not contemplate a truly fair system for the physician being reviewed. Instead of the hospital accepting the burden of proof with a reasonable standard based upon measurable guidelines for quality infractions, the bylaws shift the burden of proof to the physician and create a nearly impossible

standard to overcome. The physician typically has the burden to prove that the hospital's decision was arbitrary and capricious. Some bylaws even state that the physician must prove that there was no material basis for the action or there was a complete absence of facts in the record to support the action. An utterly biased, sloppy, negligent and mistake-riddled report by an outside reviewer still cannot be overcome by this enormous burden if there is just a shred of truth in the report.

Practical Effect

As the case law outlined above illustrates, the physician's economic competitors and antagonists can initiate the peer review process, retain outside consultants and virtually direct the outcome of the report that will form the basis of the hospital's adverse action. After the antagonist's bias, conflict of interest, self-interest, direct economic competition and retaliation motives are all effectuated, they are immaterial and not reviewable by the courts, since all of those problems purportedly can be remedied by retaining a three-member independent panel to conduct the hearing.

Most fair hearing panels are truly independent. But, even if the panel calls "balls and strikes" fairly, the burden of proof and standard of review are so high it cannot be overcome practically. There is no legal remedy or recourse to the physician under the "totality of the circumstances" test. Hospitals have figured out that all they need to do is establish an independent fair hearing panel, give minimal due process at that final phase of the case, and their immunity will be intact.

JCAHO Doesn't Care

The JCAHO accreditation manual for hospitals contains medical staff standards. One standard requires "mechanisms, including a fair hearing and appeal process, for addressing adverse decisions for existing medical staff members and other individuals holding clinical privileges for renewal, revocation, or revision of clinical privileges." When discussing the broad HCQIA immunity and typical hospital bylaws burden shifting and standard setting procedures that are anything but fair and balanced, JCAHO staff take the position that they "don't care about detail" even if, as applied, the physician has no chance to overcome the standards.

Courts Don't Care

Although courts have no hesitancy involving themselves in the intricacies of physician practice in the context of medical malpractice liability, courts take a contrary view when physicians seek redress as a result of faulty peer review and retaliation. In *Lyons v. St. Vincent Health Center*, Commonwealth Court stated: "It is not up to the courts to second-guess hospitals in their decisions as to the best way to deliver services; it is up to the institution itself."

Early Intervention Strategy

A physician subjected to peer review may have little chance of surviving unless early and aggressive measures are taken. Understanding the case law and limitation on judicial remedies, it is prudent for the physician and counsel to quickly retain the best conceivable expert in the subject area to address the outside reviewer report. In many cases, it becomes very clear that the outside reviewer's report sig-

nificantly overstates quality of care infractions, is based on no published peer reviewed medical journal articles or positions, and is academically pedantic without taking into consideration reasonable and acceptable standards of care.

Successful resolution using this strategy can be achieved with minimal disruption to the physician, including perhaps CME and monitoring, without causing a damaging Data Bank entry.

Statewide Independent Peer Review

The process described in this article has led many physicians, and some organizations, to propose a statewide peer review requirement that would utilize independent, non-biased peer review organizations that make judgments based upon clearly acceptable standards, taking into consideration reasonable differences of opinion. Like a physician being judged for a licensure infraction, the burden of proof would remain on the entity seeking to impose discipline (the hospital) with at least a preponderance of the evidence standard, if not a clear and convincing standard. Only this level of independence would balance the playing field and return quality of care to the forefront of peer review.

Charles I. Artz, Esq., is the founder of the law firm Charles I. Artz & Associates, located in Harrisburg, Pa.

APPENDIX H

OVERTREATED

Why Too Much Medicine Is Making Us Sicker and Poorer

Shannon Brownlee

BLOOM SBURY

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botched several sex-change operations and cut off the wrong leg of a man who subsequently developed gangrene and died. An orthopedic surgeon became fixated on doing more surgeries than any other physician in his group, sometimes working eighty hours a week to keep up his productivity. The more surgeries he did, the sloppier he got, until he was routinely committing errors and getting sued for malpractice. In one case, he put in the wrong size screw to repair a patient's bone and refused to correct it when the head of the screw poked through the patient's skin. It's tempting to lay all medical error at the feet of bad doctors, but that can't be the whole story, as Harvard surgeon Atul Gawande points out, for the simple reason that good doctors make mistakes too. Studies of specific types of medical error suggest that it is not just a small subset of doctors who commit them, a rotten few who are responsible for all the problems. Rather, every physician is destined to make at least one horrible mistake in the course of a career—and most will carry the memory and shame of it for the rest of their lives. It isn't just doctors who err. Virtually every person who has direct responsibility for the care of sick people falls down on the job sometimes, and the more people involved in an individual patient's care—and the more procedures the patient undergoes—the more likely it is that somebody in the medical supply chain is going to blow it. Just think for a moment about the sheer number of people who have a hand in whether a patient lives or dies. There are the orderlies who must deliver blood samples to the lab on time and the pathologists who must correctly identify infectious agents so doctors can prescribe the right antibiotic. Pharmacists have to provide the right drug at the

right dose to the right patient. Somebody has to scrub down every bacteria-harboring nook of an operating room, thoroughly sterilize equipment and linens, stock supply closets, fill soap dispensers, and maintain heart monitors and ventilators. Every single person must do his or her job right every single time or risk the well-being of patients. When you think about how many people touch a patient, either directly or indirectly, and how many tasks they must perform with precision in order to keep patients safe, it' s hard not to wonder how patients ever leave at all.

THREE Your Local Hospital 72

To REACH SHASTA Regional Medical Center, just drive north from San Francisco on Interstate 5 for four hours, until you see Mount Shasta, floating over Siskiyou County in its permanent cloak of snow. The hospital sits in the middle of downtown Redding, near a bend in the winding Sacramento River. Known as Poverty Flats in the early nineteenth century, Redding was first settled by miners and loggers, who stayed until the mines were tapped out and the redwoods and pines were all cut down. The town revived in the mid-twentieth century. When it became a mecca for fishermen, hikers, and skiers headed for nearby Shasta and Trinity lakes, Lassen Volcanic National Park, and snowcapped Mount Shasta. Tourism is now one of two main businesses in this town of ninety thousand residents. Between them, Shasta Regional Medical Center and Mercy Medical Center employ more than two thousand people, and generate nearly one hundred million dollars a year in revenue. Dr. Patrick Campbell arrived in Redding with his wife and two children in 1993 less than two years out from his internship and residency at the University of California, Davis.

Campbell had been working in an urgent care facility in Sacramento when he was recruited by Redding Medical Center (which would be renamed Shasta Regional Medical Center in 2003). Redding offered a two-year salary guarantee, which would give Campbell time to build a practice and payoff medical school debts. From the hospital's perspective, good relations hips with primary care physicians like

Campbell were a matter of branding, well worth the recruitment costs: primary care doctors who were loyal to Redding Medical would admit patients to the hospital and refer them to the hospital's specialists, especially those in its busy cardiac program. To Campbell, Redding seemed to offer a good life. The crime rate was low, the schools were good and the area was beautiful. He could have a small-town practice that would let him get to know his patients over the years, while still having access to a modem, high-tech hospital. Campbell's high hopes and idealism at the outset of his career made the events that would unfold in Redding over the next decades the lawsuit he would file in 2002, the evidence of malpractice and fraud committed by several heart specialists at Redding Medical that he would uncover, and the town's anger at him for exposing two of its most prominent physicians seem all the more surreal. After blowing the whistle on the hospital and its specialists, he would lose practically everything he valued, his medical practice, his family, and his home. The tale of Campbell and Redding Medical Center tells a larger story about the forces that drive all hospitals to deliver unnecessary care—and how difficult it is to rein them in. Campbell grew up in Portland, Oregon, the son of a secretary and a customs inspector, the

first person in his family to go to college. An accomplished violist in high school, he entered Levis and Clark College with a full music performance scholarship. But after two years of college and a move to California, the early dream of an orchestral music career faded. He enrolled at the University of California, Santa Cruz, and switched to natural sciences. After an undergraduate degree in chemistry and three years as a graduate student, he finally settled on medicine, enrolling in medical school at the University of California, Irvine, where he met his wife. Both Campbell and his wife went into primary care. an idealistic decision at a time when more and more of their classmates were choosing to enter specialties where the money was much better. One of the first doctors Campbell met in Redding was a cardiologist, Chae Hyun Moon. The son of a Korean physician, Moon was a more ambitious breed of doctor. According to the New York Times, he graduated in 1972 from the College of Medicine at Yonsei University in Seoul and completed an internship and residency at Metropolitan Hospital Center in New York.

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His forceful personality and constant availability allowed him to quickly build a thriving practice in Redding. When Moon arrived in northern California in the early 19 8 0 5, all invasive cardiac services-cardiac catheterization, angioplasty. and open-heart surgery—were being done in bigger cities like Sacramento, two hundred miles away. Moon pushed for a cardiac catheterization laboratory—a special room containing the equipment needed to perform such procedures as balloon angioplasty—and open-heart-surgery capability in Redding. First Mercy Medical

Center and then Redding Medical opened labs, followed by an open-heart-surgery program, in 1987. Five years later, Moon and Fidel Realyvasquez, Jr., a Stanford-trained cardiothoracic surgeon were the dominant figures in their respective specialties. Together, the men built the California Heart Institute within the once-sleepy Redding Medical Center. Primary care physicians sent their patients from all over northern California, from tiny towns like Weed and Paradise, and from as far away as southern Oregon. Moon was always willing to accommodate another patient. As he would later tell the Sacramento Bee. "When these guys call me up day or night or holidays, it doesn't matter. I am in a health profession to save lives." Both heart specialists were workhorses, but Moon especially so. He focused his practice on catheterization, an invasive procedure that involves snaking a thin catheter, or tube, up through a major blood vessel in the groin into the coronary arteries, the blood vessels that supply the heart muscle with oxygen. Moon also performed balloon angioplasties, threading a tiny balloon up a wire inside the catheter. When the balloon was inflated, it could smash a clot against the arterial wall, allowing blood to flow freely once again. By the 1990s, cardiologists were also employing stents, tiny mesh tubes that could prop open a blockage inside a coronary artery. Moon sometimes performed as many as a dozen cardiac catheterizations in a sing le day-four to five times the number his peers in northern California were performing. In one year, he performed more than eight hundred invasive cardiac procedures. Between June 2001 and 2002, he billed Medicare for four million dollars. At its peak, Redding Medical Center was Performing nearly eight

hundred open-heart surgeries per year—many of them done by Realyvasquez.

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With the enormous volume of procedures came high incomes and lavish lifestyles. Moon owned a rambling hilltop estate on the west side of Redding, with a view of Mount Shasta and No Trespassing signs posted at the bottom of the driveway. Realyvasquez lived on the east side, at the end of a tree-lined street behind an electronic gate. The doctors were popular figures in town. Realyvasquez donated his collection of fifty original Ansel Adams prints to a local museum. For eight years, Moon donated five thousand dollars annually to a scholarship for Shasta High School graduates interested in science or medicine. In a letter to the editor of the Redding Record Searchlight, the local paper, a resident wrote, "How lucky we have been that Dr. Moon chose this country to practice in." In the summer of 1993, a new patient, Mary Rosburg, came to Patrick Campbell with a multitude of physical complaints, including mild chest pains and shortness of breath. Rosburg and her husband spent summers living in their trailer in Trinidad, a small resort town on the California coast, just north of Eureka. Because she was having chest pains, Campbell gave Rosburg, who was in her sixties, a stress test, which involved asking her to walk on a treadmill while hooked up to a cardiac monitor. The test was inconclusive, but out of an abundance of caution, he referred his patient to Moon. Campbell assumed that the specialist would "work up" Rosberg that is, give her a series of mildly invasive tests, including another kind of treadmill test, that would help determine whether her complaints indicated heart disease. Instead, Moon went straight to a coro-

nary artery catheterization and promptly declared that she needed immediate bypass surgery and a heart valve replaced. Campbell was surprised both by the speed with which Moon used catheterization and by the diagnosis, but he assumed the cardiologist knew best. Later that same day, however, Campbell got another call, from a young cardiovascular surgeon who was a newly arrived partner of Realyvasquez's. In that doctor's opinion, Rosburg did not need surgery. Campbell was startled, but as a primary care physician just starting out in the community, he didn't feel he was in any position to quest ion Moon's judgment. He suggested the surgeon talk to Moon directly. The next morning, Campbell's patient under-went the operation. Her recovery was

uneventful, hut several weeks later, while in Trinidad with her husband, Rosburg abruptly developed severe chest pain and shortness of breath. Flown back by helicopter to Redding, she was found to have a large blood clot on her new heart valve and underwent emergency surgery that night to replace it. Rosburg went into acute kidney failure and died within a week. Shaken by the death of a patient who had been essentially healthy just three months earlier, Campbell wondered if perhaps the surgeon who had called him had been right-that Moon's diagnosis had been incorrect. He concluded that he was in no position to review the records independently, and the surgeon in question left the area after one year. But after witnessing further examples of Moon's quickness to send patients to the cath lab and recommend open-heart surgery. Campbell began to worry in earnest that Moon and his group were being far too aggressive in their management of cardiac patients. Two years

later, Campbell would have hard evidence that patients were being given unnecessary care by the cardiologists in Moon's practice. During a routine office visit, Emma Jean Montgomery complained to Campbell about chest pain. Campbell reports that he sent her to one of Moon's partners. The cardiologist performed a stress test, then catheterization, and told Campbell by phone that the patient had severe, three-vessel coronary artery disease and needed immediate bypass surgery. The surgery was done the next day. When Campbell received the written report from her catheterization, two months after her surgery, he was shocked to see that the cardiologist had indicated that the patient had only mild to moderate coronary artery disease and that her chest pain was not caused by her heart. Not knowing which version to believe, Campbell obtained the images of her heart that were taken during her procedure and looked at them with Dr. Roy Ditchey, a local, board-certified cardiologist who had just relocated to Redding. Campbell says that Ditchey agreed: The woman's coronary arteries were not severely blocked, and she had not needed surgery More than once, Campbell and other physicians who were concerned about the hospital's cardiology program and its doctors would complain to Redding Medical Center administrators. At least once, a review was promised.

but over the years, as far as Campbell could tell, one was never actually undertaken. In the end, Redding Medical Center would be forced to shut down its cardiac program, after Campbell finally succeeded in alerting the Federal Bureau of Investigation and the Department of Justice. Medical records seized from the hospital were given to several outside heart

specialists, who found that in twenty-seven years at Redding, Moon had catheterized some 35,000 patients, a huge number for just one physician working in a lightly populated, largely rural area. In the opinion of the outside specialists, between one quarter and one half of the patients who underwent catheterization or surgery at Redding Medical Center had been operated on inappropriately. Justice Department documents stated that at least 167 patients had died during cardiac surgery, or shortly after, as a direct result of the Redding doctors' aggressive treatment. Either the patients had been too weak to withstand the surgery, or the doctors had been negligent, or they had committed errors, sometimes in haste to go from one patient to the next. In May 2006, the California State Medical Board moved to revoke Moon and Realyvasquez's licenses. By then Redding Medical's parent company, Tenet Healthcare Corporation, had agree to pay $59.5 million to the federal government to settle charges of Medicare fraud, at the time the largest settlement made by a health care company. A flurry of news reports appeared across the country, tracking the spectacular fall of Redding Medical Center. Most of the articles interpreted the events as an exceptional example of doctors run amok, or an isolated case of Medicare fraud, or an especially egregious episode in the ongoing saga of for-profit health care. But the story of a small hospital in northern California symbolizes a flaw in American medicine that goes far deeper—and is shared by nearly every sing le medical institution in the country.

No margin, no mission

The one concept that the media missed in covering the events at Redding Medical Center was that most

hospitals deliver unnecessary care. As patients, we want to believe that places like Redding and doctors like Moon

and Realyvasquez represent the rare case, and that a for-profit hospital so busy making money that its administrators did not want to acknowledge what was going on in their cardiac center is the exception, not the norm. Unfortunately, Redding Medic al and its doctors were simply outliers at the far end of the spectrum of useless, unnecessary and potentially dangerous care that hospitals provide (even as they simultaneously fail to deliver other kinds of care that patient s need). Unnecessary care, it turns out, is inevitable in a health care system like ours, partly because of the way hospitals are paid. All hospitals need to make money, and for the most part, as we've seen, hospitals and the physicians who work in them get reimbursed for how much care they deliver, rather than how well they care for patients—let alone how efficiently they deliver that care. When hospitals and doctors give patients medical procedures and tests they don't need, or when they fail to give patients care they do need, they are responding to the perverse incentives built into the byzantine and often—precarious reimbursement system that keeps them all afloat. In the days before health insurance and Medicare, most hospitals were run by religious charities, which operated under the motto "No margin, no mission." Their mission, of course, was tending to the sick, regardless of the patient's ability to pay; they tried to earn a small margin on the patients who could pay in order to cover the cost of their mission. Today, hospitals still need to run a profit to stay open, even nonprofits, which make up more than

three quarters of the more than five thousand hospitals in the United States—and most still turn to paying (or insured) patients in order to do so. From the humblest rural clinic to the most prestigious academic center, nonprofit hospitals generally earn at most between 2 and 6 percent profit on annual revenues, in part because forty-s ven million Americans under sixty-five, or about one in six of us, have no health insurance. At most nonprofits, about 3 to 5 percent of patients are uninsured; at public teaching hospitals, it's a whopping 15 to 20 percent. In 2003, hospitals reported losing twenty-five billion dollars providing care for which they received no compensation. (Outside researchers suggest hospitals may be inflating their losses, which may be closer to sixteen billion dollars.)

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With its ideological preference for market-driven solutions. the Reagan administration was not about to approve price controls on hospital payments. Instead, the president signed a plan to impose the DRG system, an entirely new, draconian payment plan intended to create incentives for efficiency and reduce the number of details over which government and hospitals could quibble. The fee for each diagnosis group is set to reflect the average cost of treating that condition in an efficient hospital. If a patient is sicker than average and requires extra care, the hospital eats the difference. If the patient is healthier than average, or the hospital gets him back on his feet more quickly than average and he consequently costs less than average, the hospital gets to keep the change. The DRG system succeeded in providing a market incentive for efficient hospitals to make a small profit, while forcing inefficient hospitals to cut

expenses. Many hospitals responded by shutting down excess beds and slashing their lengths of stay, which had stretched out during the cushy cost-plus years. The system slowed the rate at which Medicare spending was rising to 8.6 percent between 1983 and 1984, the smallest annual increase since the program began. The following year the rate of increase dropped to 5.5 percent. (The rate of increase for hospital payments went to zero the year that Redding Medical Center's shenanigans came to light. with hospitals bending over backward to avoid over-charging Medicare.) But the DRG system also had an unexpected side effect, one that has helped drive the delivery of unneeded care in certain branches of medicine. Even though DRG fees are supposed to reflect actual costs. in reality they overpay for many procedures, especially many surgeries. At the same time, they underpay for other kinds of care. Take cardiac bypass, an exceptionally profitable surgery. in 2002, Medicare paid $24,000 per bypass surgery with cardiac catheterization while the average cost per case, according to a report put out by the Medicare Payment Advisory Commission (MedPAC), was $ 14,400, leaving $9,600 profit for every by-passed patient. Other cardiac procedures offer even higher margins: Replacing a heart valve, the surgery Patrick Campbell's patient Mary Rosburg underwent, can yield as much as 60 percent profit. The net profit hospitals make from these procedures drops when Medicare patients are sicker, of course, but even so, the

most common cardiac procedures typically performed on a heart attack patient earn about 6 to 16 percent over costs from Medicare reimbursement and more

than one hospital has made its entire margin on invasive cardiac procedures alone. Most private insurers don't use the DRG system, but rather a combination of negotiated payments and per diems that wind up being more generous in some markets than Medicare—and they too overpay on many procedures. From private payers, hospitals can reportedly make around $ 20,000 for an angioplasty procedure, about 40 percent of which is profit. On the flip side of the profit equation, the DRG payment for treating a heart attack patient with drugs alone and no surgical intervention—which for many patients is just as effective—produces about an 11 percent loss for the average hospital. What all this means is that any hospital administrator with an ounce of good business sense is going to want to maximize the number of patients in profitable service lines, which they have taken to calling "centers of excellence," whether or not they are, in fact, excellent. Even at academic medical centers, administrators exert subtle pressure on the physicians working in profitable departments to keep up their productivity by performing more-profitable procedures. In this sense, a hospital is no different from any other business. In recent years, IBM has shifted its focus from selling hardware to servicing large database systems where profits are higher. An even better analogy for the hospital industry is a low margin, high-volume business like personal computers. Dell earns only about 5 percent profit on each computer it sells, but it sells millions and millions of them. Similarly, hospitals want as many "bed turns:" or as much "throughput," as possible in their profitable departments. The best way to accomplish this is to expand the capacity of high-margin departments to increase volume. You can think of it as the Willie Sutton

strategy: Willie Sutton robbed banks because that's where the money is; hospitals invest in their money-making product lines because that's where the profit is. Yet, when hospitals focus not on profits but instead on providing care that helps patients, they often wind up being punished financially Several hospitals around the country have experimented with integrated, supportive

Investing in profit, not health. All of this goes a long ways in explaining why, in 1998, Redding Medical Center decided to expand its moneymaking product line—the cardiac procedures being performed by Realyvasquez and Moon. That year, the hospital earned $50 million in pretax profits, most of it from the California Heart Institute. "We were beyond full: one former administrator would later tell the New York Times." We were flying. The hospital constructed a five-story addition, known around town as "the Tower," much of which was devoted to expanded cardiac facilities. The Tower allowed Moon and Realyvasquez to recruit other cardiologists and surgeons to the area-and to bring in more patients. The cardiology specialists were not actually employed by the hospital; they had private practices and what's known as "admitting privileges," a relationship that is beneficial to both physician and hospital. Once known as the "doctor's workshop," a hospital is a little like a hotel filled with nursing staff, technology, and beds, where physicians are granted the privilege of admitting and treating patients. For hospitals, doctors are the medical equivalent of rainmakers in a law firm, the people who bring in the paying customers and most hospitals bend over backward to attract and keep physicians who can bring in patients

who are insured. "Hospitals need to understand who their customer is—the doctor who admits patients," as one neurosurgeon aptly puts it. With so much riding on the cardiac team, Redding administrators and the hospital's parent company, Tenet Healthcare, stroked and pampered Moon and Realyvasquez. The hospital appointed Realyvasquez chairman of cardiothoracic surgery and made Moon chairman of the cardiology department. Moon was also a member of the hospital board, and was eventually made head of the committee charged with overseeing the quality of cardiac care. The hospital sponsored golf tournaments to benefit the cardiac unit, sometimes offering Moon the use of its emergency helicopter to fly to the golf course. Moon's success and prestige gave him unusual clout for a physician; at one point, he was instrumental in persuading Tenet to dismiss a hospital executive. "No one would ever want to take [Moon] on," a former Redding administrator told the New York Times. "Moon was Redding Medical Center, and he knew it."

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By '999, Campbell had stopped sending patients to Moon if he could avoid it. He left his group practice and moved to another office, preferring to send his patients to Mercy Medical Center, the hospital across town. Still, he felt compelled to call attention to the situation at Redding. He strongly suspected that Moon, Realyvasquez, and their colleagues may have been charging Medicare and Medi-Cal, the state's Medicaid program for unnecessary procedures, not to mention putting patient s at terrible risk. In March, he approached a local Redding attorney, asking his advice about how to get the government to investigate the hospital and its cardiac team. The attorney,

Jerrold Pickering, a longtime Redding resident who was a patient of Campbell's at the time, listened to the doctor's story for two hours before promising to look into the matter. Over the next two weeks, Pickering made several confidential inquiries to local Medicare officials, outside physicians, and the local district attorney's office. The lawyer then wrote Campbell a letter, telling him that the public authorities were not interested in pursuing the case. "The Medicare people shuffled around and around ... and were not really interested unless someone handed them a case fully worked up, "he wrote. The district attorney was equally disinclined to pursue the issue, according to Pickering, even after he mentioned the death of one of Campbell's patients. Several of the people Pickering contacted knew about the problems at Redding Medical Center, wished any whistleblower well, but "would undoubtedly disappear when the first shot was fired. The conclusion is inescapable: Do not blow any whistle! Period. Rationale for this is: (1) you would be very alone, (2) there is too much money involved, (3) except for the victims and/or their families, no on e cares, and (4) you would instantly find yourself with a bunch of new vigorous enemies." Several of those predictions would turn out to be painfully accurate for Campbell, who ignored the lawyer's advice and continued to search for a way to get Medicare to pay attention. Later that year, he came across an article in the magazine Medical Economics about a successful physician whistleblower and the federal False Claims Act, which is intended to encourage employees of companies that do business with the federal government to report fraud and abuse. Campbell called the physician, who referred him to

a New York law firm that specialized in whistle-blower-cases. The firm told Campbell he needed more cases to persuade the government that there was a serious problem worth investigating. But Campbell was unable to get other Redding physicians to produce any cases, even physicians who in private complained about Moon, Realyvasquez, and Redding Medical Center. By the summer of 2001, Campbell was deeply discouraged. He'd exhausted every option he could think of for alerting the authorities. His wife was fed up with his obsession, and he still had a busy primary care practice to tend to. A year later, Campbell got word that an FBI agent was nosing around town, asking questions after a few patients or their families had complained to the agency about the cardiac program. Throwing his lawyer's advice to the wind, Campbell called the agent. That was on a Thursday afternoon in August; the next morning he was sitting in the agent's office in Redding. Worried that the FBI agent would not believe him, Campbell arrived with over sixty pages of documents. After showing the agent his material, Campbell steered him to a nurse and two other physicians, who would eventually back up his claims that Redding's cardiac team was performing necessary cardiac procedures. On October 30, 2002, the FBI filed a sixty-seven-page search warrant affidavit with a judge, based largely on Campbell's information. That same day, more than forty agents from the FBI and the federal Department of Health and Human Services showed up without notice at Redding Medical Center and the doctors' offices and seized thousands of patient records and other evidence. Two weeks later, the stock price of Tenet Healthcare had tumbled from nearly fifty dollars a share to fifteen dollars. The

Justice Department's outside experts and a cardiologist hired by the state medical board would find a pattern of unnecessary and sometimes negligent care that represented "an extreme departure from standards of medicine," according to one physician who reviewed the records. In one case at Mercy Medical Center in 1996, Moon left a sixty-seven-year-o ld man who had suffered a massive stroke on the catheterization table, in the care of nurses without adequate instructions, and returned to his office. The man died soon thereafter. Moon would later defend his actions by saying he had done everything he could by picking up the phone and calling in a

neurologist and a critical care specialist. When brought before peer review committees at Mercy to explain his actions, Moon fought back, ultimately filing lawsuits in state and federal courts against the hospital. The suits were eventually dismissed. Other patients of Moon and Realyvasquez survived but suffered long lasting, debilitating effects from their unnecessary surgeries. A local rancher named Stephen Hunt was only thirty-eight years old when he walked into the emergency room at Redding Medical Center just before Christmas in 2001, complaining of blurry vision in one eye. Hunt knew he had high blood pressure, but he was shocked when Moon told him he needed immediate bypass surgery—that he could suffer a heart attack and die on his way back to his car. Moon also told him there just happened to be an opening in the hospital's operating schedule on Christmas Eve. Hunt went ahead with the surgery. When the Justice Department gave Hunt's medical records to outside cardiologists, they found no evidence that the surgery had been needed. Hunt's

blurry vision cleared up once his blood pressure was successfully treated with drugs, but his life would never be the same after his surgery. He suffered a hernia at the incision site, which meant he could no longer do the physical labor of ranching: the fencing, bucking hay, and moving cattle. Five years later, he lost his ranch. On August 4, 2003, Tenet Healthcare Corporation agreed to pay $54 million to settle fraud charges brought by the federal government. In return, Redding Medical Center and Tenet were granted immunity from criminal prosecution. Ultimately, Tenet paid nearly $60 million to settle federal fraud allegations. and the Department of Health and Human Services permanently banned Redding Medical Center from receiving Medicare. Tricare (which insures members of the military), or Medi-Cal payments, effectively forcing Tenet to sell its former flagship hospital. The company eventually agreed to pay an additional $395 million in restitution to more than 769 patient s and their families who sued the company. In all, Tenet would pay the federal government more than $900 million to settle charges of unlawful billing practices at Redding and other hospitals. Shareholder lawsuits amounted to $ 2 15 million. In January 2003, Moon voluntarily suspended his practice. The California State Medical Board opened an investigation.

Moon and Realyvasquee agreed to pay $ 1.4 million each in fines to the federal government, in lieu of criminal prosecution, while their Medicare billing privilege s were revoked. There are many lessons to be drawn from the story of Redding Medical Center, beyond the obvious fact that physicians don't like to point fingers at colleagues, even when their reticence

allows patients to be harmed. But perhaps the most important lesson concerns the powerful effect that distortions in the reimbursement system can have on the decisions that hospital administrators make about how to invest capital resources. These distortions, coupled with policies dating back before the beginning of Medicare that built up the number of hospital beds until the early 1980s, have conspired to leave some cities, or parts of cities, with a surplus of certain kinds of beds and facilities—while simultaneously creating a shortage of others. In Los Angeles, for instance, there are two and a half times more intensive care unit beds per Medicare recipient than there are at the renowned Mayo Clinic, in Rochester, Minnesota, where nobody would argue that patients get substandard care. The result of this surplus of ICU beds in Los Angeles has meant that doctors are more likely to put patients in the ICU, whether or not they really need to be there. This kind of overinvesunent in profitable service line s can be seen in cities and towns across the country, in New York, Miami, and Los Angeles especially—precisely the cities where Jack Wennberg's group has found the highest rates of unnecessary care. We all wind up paying for it, as this overinvestment drives up costs for Medicare, state Medicaid programs, and private insurers. Meanwhile, more than a hundred emergency rooms around the country have closed in the past decade, victims in part of rising rates of uninsured patients appearing at their doors. At hospitals that have kept their emergency doors open, administrators have not been eager to add the additional ER beds that are often so desperately needed, because that would mean caring for more uninsured (and unprofitable) patients. Many cities now face a shortfall of emergency services, and hospitals rou-

tinely divert ambulances because their emergency departments are completely full. In Cincinnati, for example, diversions were so rare before 1998 that the city didn't even track them. By 2002, the total amount of time the city's hospitals were on divert

status had jumped to 1,970 hours annually, and the problem just keeps getting worse. In the month of December 2003 alone, emergency rooms were on divert status for 1.935 hours. That's the equivalent of nearly eighty-two days. I caught up with Patrick Campbell in June 2006, when he was living in Eugene, Oregon pulling twelve-hour shifts as a hospitalist overseeing the care of patients admitted to Sacred Heart Medical Center. When I spoke with Campbell over the phone, he recalled the events shortly after the FBI's 2 0 02 raid in a tone of voice that veered between incredulity and resignation. "I remember a day after the raid, I had to go see a patient over at [Redding Medical Center], and people were looking at me with hatred," he said. "Within a week, everybody in Redding knew who had talked to the government, even though I was identified on the FBI affidavit only as 'D I.' "Stories appeared in the Redding Record Searchlight, reporting expressions of outrage among the local citizenry-not at Moon and Realyvasquez's alleged perfidy, but rather at their persecution by the federal government. The paper quoted Rhonda Arnold, a medical assistant in Moon's office, saying, "I've never met a man as honorable as Dr. Moon." Colleagues of the doctors said it was an injustice that patients would be "cardiac cripples" if not for Moon and Realyvasquez. On November 8, 2002, nine days after the raid, Campbell filed a qui tom (whistleblower) suit with the u.s. district court,

in Sacramento. A qui tam lawsuit is typically filed by a private party, alleging fraud against a federal agency. If the Justice Department investigates and the fraud is proved, it enables the government to recover up to triple damages and substantial penalties from the defendants—while the whistle-blower can potentially receive a portion of the government's recovery. By then, Campbell was pretty sure he was going to need the money to start over in another town. Patients had left his practice; colleagues avoided him. The town of Redding was angry with him. The state medical board would initiate, and ultimately drop, disciplinary proceedings against him, putting hi s medical license at risk, after a patient complained that Campbell had given the patient's confidential Your Local Hospital 93 records to the FBI without consent. His popularity did not improve when the hospital began laying off employees. At one point, a group of nurses threatened to sue him for loss of employment. In June 2003, eight months after the raid, Campbell was stunned to learn that the Justice Department had moved to dismiss his whistle-blower suit in favor of another qui tam suit that had been filed just three days before his. The first-to-file whistle-blower was a Catholic priest named John Corapi, who had gone to Moon in June 2002 for what he thought was a routine cardiac checkup and had been told, like so many of Moon's patients, that he would die without immediate surgery. Unlike many patients, Corapi got a second opinion- in Las Vegas, where an old college buddy, Joseph Zerga, was an accountant. The doctors there told him that he had no significant coronary artery disease. When Corapi and Zerga complained to the Redding Medical Center CEO and got the brush-off they went to the FBI. The priest's legal standing as a

whistle-blower was questionable. The Justice Department was suing Tenet Healthcare and the doctors on behalf of Medicare; Corapi, who was in his fifties, wasn't old enough to be a Medicare recipient. The priest's contribution to the FBI's investigation consisted only of his own medical records; he had no personal knowledge of any other cases, and his case involved only an unnecessary cardiac catheterization and a recommendation for bypass surgery. The sixty-nine pages of documents that Campbell plunked down on the desk of the FBI agent, by contrast, contained case histories covering a ten-year period; a record of Redding Medical administrators' ignoring multiple efforts to bring Moon and Realyvasquez's actions to their attention; names of physicians and a nurse who could corroborate his story; and even a glossary of medical terms. Even so, the Justice Department took the position that Corapi and Zerga were the sole whistle-blowers, because they beat Campbell to the courthouse. In August, the court granted the Justice Department's motion to throw out Campbell's qui tam suit and subsequently enter into the $54 million settlement with Tenet Healthcare. Meanwhile, Corapi and Zerga stood to receive the entire 15 percent of the settlement owed to a whistle-blower, worth more than $8. 1million.

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It would take more than two years for Campbell and his lawyer to get the Justice Department's decision to remove him as a whistle-blower reversed. In the meantime, Campbell's practice In Redding dried up completely. His marriage foundered—"J wasn't the easiest person to live with," he said and in 2005, he left his wife and two children In Redding and moved to Eugene. When his lawyer filed an objection to the

Justice Department's decision, assistant U.S. attorney Michael Hirst, the prosecutor in the case, accused Campbell of being "driven more by greed than indignation." The prosecutor praised Corapt and Zerga, saying publicly, "Their willingness to blow the whistle on fraud resulted in our putting a stop to the surgeries and recovering $54 million." "That was a low point," Campbell told me. "It played out in the local paper as a battle between competing whistleblowers, a doctor and a priest, ducking it out in the courts." In November 2005, the court reinstated Campbell's qui tam suit and he agreed to settle for half of the whistleblower bounty, giving him nearly $4.5 million, before taxes and attorney's fees. Seven months later, in 2006, his wife and kids were driving up from Redding for a visit over the Fourth of July weekend. Campbell had not decided what he would do next. In the weeks leading up to the settlement, he had imagined that it would bring some sort of relief, a sense of closure, and maybe even a small measure of vindication. But when I spoke with him, Campbell sounded tired. Some days, he said, he thinks he will set up a new practice in Eugene or elsewhere; on other days, he wants to abandon medicine entirely and embark on a new career. Neither Moon nor Realyvasquez has ever admitted any wrongdoing. Shortly after the raid. Moon appeared genuinely devastated by the charges. Telling reporters his only goal had been to keep his patients safe from heart disease. He wept when a group of supporters strung up a banner that said, WE SUPPORT OUR DOCTORS! outside the courthouse. Maybe Moon and Realyvasque2 and the hospital were deliberately bilking Medicare, as the Justice Department's charges against them indicate. Or maybe, as Moon

and Realyvasquez claim, they were making judgment calls within the wide latitude Your

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permitted by the art of medicine, the uncertainty of cardiology. If that's the case, then the saga of Redding Medical Center points to the desperate need in medicine for clearer standards and better evidence for what works and what doesn't. The story of Redding also highlights the need fat a new way to pay doctors and hospitals, a system that doesn't allow financial imperatives to propel clinical decisions.

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Too many patients. Give them the time to practice preventive medicine. (VHA primary care doctors are responsible for about fifteen hundred patients, at least five hundred fewer than the average internist or family physician.) Use information technology to improve coordination among doctors. Make hospitals and doctors accountable by measuring their performance and the outcomes of their patients. And finally, gather evidence for what works and what doesn't. We could call this strategy CARE, for coordination, accountability, electronic medical records, and evidence. While the tasks are clear, implementing CARE around the country won't be simple. In order to do it, we have to rethink the way we pay doctors and hospitals. The first step is for Medicare to address the way it overpays for certain procedures, like radiology and bypass surgery, and underpays for less-intensive care. The current system encourages hospitals to invest in expensive doctors and beds and technology that aren't necessary-ly what patients need. But there are other ways the payment system makes it hard for doctors to coordinate their care and

leads to unnecessary hospitalizations. Take the example of caring for diabetics. More than thirty million Americans have diabetes, the product of our ever-increasing girth and sedentary lifestyle. Over 60 percent of Medicare spending goes toward patients with chronic conditions like diabetes and heart disease, and the majority of the money is spent on hospitalizations for complications that could have been prevented with proper care. But keeping diabetics out of the hospital requires constant monitoring. Diabetics who fail to control their blood sugar are more likely to go blind, suffer heart attacks, or have a leg amputated because of a wound that won't heal. Preventing those complications isn't rocket science; it just takes constant work. Patients need to learn to eat better and exercise. They need to monitor their blood sugar and take their insulin or other drugs. They need to see an ophthalmologist regularly to check for damage to the retina and a podiatrist to ensure they are caring for their feet. And their doctors need to check their hemoglobin on a routine basis to make sure they are controlling their blood sugar at home. How often does all of this coordinated care actually happen? Outside of a few systems, like the VHA, Group Health, and Kaiser, rarely at best. Let's

look at just one piece of this puzzle, monitoring hemoglobin. If you have diabetes, your chances are about one in four that a doctor will actually perform that test, let alone teach you to check your own blood sugar level on a regular basis. According to a recent RAND Corporation study, failing to get their blood sugar checked leads an estimated twenty-six hundred diabetics to go blind every year and another twenty-

nine thousand to experience kidney failure. Doctors and hospitals don't neglect to treat diabetics properly because they are lazy or incompetent or don't care about their patients. They fail to do it in part because the payment system punishes them financially when they do. About seven years ago, a group of idealistic doctors in Bellingham, Washington, a bucolic coastal town about an hour north of Seattle, created Pursuing Perfection, a program to help participating medical practitioners prevent diabetes and chronic heart failure and to better care for patients who already have the conditions. The program centers on multidisciplinary teams employing the best practices for counseling patients, helping them to navigate the health care system and control their diseases. It also calls for preventive measures, providing access to nutritionists and nurses to help patients learn to eat better and exercise more in order to avoid getting the conditions in the first place. The doctors have implemented information technology to allow everyone involved in a patient's care to share medical records and support disease management. Pursuing Perfection has already improved the health of many patients. Rebecca Bryson suffers from both diabetes and congestive heart failure. Before enrolling in the program she was seeing fourteen different doctors and taking forty-two medications. When her lungs would fill with fluid from her congestive heart failure, she would call a doctor's office and tell the nurse what was happening. Sometimes she would get a call back in an hour, sometimes not for a day. She landed in the emergency room routinely. Under the new plan, she has access to a nurse, called a clinical specialist, who knows her case intimately, helps her adjust her medic actions, and gets her in to see the doctor when she needs it. Bryson also has access to

her own electronic medical record, where she can note reactions to a new medication. With the help of her clinical specialist, Bryson has learned how to avoid

going to the doctor by doing things like checking on the salt in her diet if her blood pressure goes up. These simple steps have had measurable results for patients across the board, reducing blood sugar levels in diabetics and preventing crises in heart failure patients. Pursuing Perfection has not only improved the lives of patients like Rebecca Bryson, it is saving both Medicare and private insurers thousands of dollars per patient and could cut deaths from diabetes by half. But Pursuing Perfection is killing the local hospital. Between 200 I and 2008, the initiative will have cost Peace Health's St. Joseph Hospital, in Bellingham, $7.7 million in lost revenue because patients aren't being admitted as often. The county's specialists stand to lose $ 1.6 million from lost procedures and office visits, and from having to spend time with patients without being compensated. Insurers won' (pay for a nutritionist to teach diabetics how to eat properly. They pay podiatrists well to perform procedures, but not to help a diabetic learn to inspect his own feet. One group of sixty doctors, at the Madrona Medical Group, who took part in planning the initiative, have withdrawn from the program because participating will cost them too much money. This is the sorry state of American health care. Doing what's best for patients is bad for business. The problem here is not that there's no money; it's that the money flows through the system in the wrong way. Hospitals are paid for each episode of care, each hospitalization, and doctors are paid for

each office visit, each procedure. They aren't paid to coordinate the care of diabetics or heart failure patients, to hire nurses to track a patient 's weight or make sure his lungs aren't filling up with fluid, or a nutritionist to help a diabetic understand what she can and cannot eat. In order for programs like Pursuing Perfection to succeed, hospitals must work with all local doctors, not just those who are willing to lose money in order to help their patients. The way to do that is to pay them as if they were a single, integrated group, hospitals and doctors working together. But that's not how we do it. Instead, our insurers pay the hospital one fee and the individual contractors who work in it—the doctors-another. Medicare officials are well aware that their own payment system is working against the health of patients, and they have proposed a solution to the

problem of poor quality called "pay for performance," or "P4P." In phase one, hospitals receive a small bonus for monitoring their own performance on seventeen measures of quality. Most hospitals are now checking such things as what percentage of diabetics receive an eye exam once a year and how often heart attack patients are given instructions to take aspirin or a prescription for beta-blockers. More performance measures will be added to the list as the plan progresses. In phase two, hospitals will be paid another small bonus for actually improving their scores on each measure. Hospitals that are below average will eventually be fined. Medicare is also test-driving a similar plan to measure the performance of Individual physicians. Doctors fear that they will be measured on things they can't always control. Say a physician has a group of diabetics, for instance,

and she's taking great care of them, monitoring their blood sugar regularly and helping them stay out of the hospital. But one of her patients simply won't do what's necessary to keep himself healthy. He refuses to measure his blood sugar. He doesn't take his insulin. And he eats anything he wants, no matter how his doctor exhorts him to change his ways. When Medicare then measures that doctor's performance, she may look bad because of one recalcitrant patient. It's also difficult to measure an individual doctor's performance because patients move between doctors so often, and they see multiple specialists, making it difficult to assign responsibility for an individual patient to a single primary care physician. But the larger reason we shouldn't be measuring individual doctors is that it doesn't foster cooperation among them. Medicare'sP4P plan for hospitals won't either, because it focuses too narrowly on individual aspects of a web of events that must happen in order for a hospital to care properly for a patient. Focusing on a few discrete measures is like saying you are going to make a building earthquake-proof by bolting the furniture to the floor, or reform Social Security by switching to a cheaper brand of ink for writing the checks. The question is, how can we move the five thousand hospitals and eight hundred thousand physicians in this country to organize themselves into cooperative groups? One way to do it would be to allow the VHA to take over failing hospitals. My colleague Phillip Longman, in his book Best Care.